

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
22 December 2005 (22.12.2005)

PCT

(10) International Publication Number
WO 2005/120365 A1

(51) International Patent Classification⁷: **A61B 17/32**

Cambridge CB3 7RF (GB). **ALDEN, Don** [US/US]; 1312 Nelson Way, Sunnyvale, CA 94087 (US). **SCHUMANN, Matt** [GB/GB]; The Old Horse Yard, Comberton Road Toft, Cambridge CB3 7RY (GB).

(21) International Application Number:

PCT/US2005/019445

(74) Agent: **TUNG, Hao, Y.**; Heller, Ehrman White & McAuliffe LLP, 275 Middlefield Road, Menlo Park, CA 94025-3506 (US).

(22) International Filing Date: 3 June 2005 (03.06.2005)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/577,412 3 June 2004 (03.06.2004) US
60/577,376 3 June 2004 (03.06.2004) US

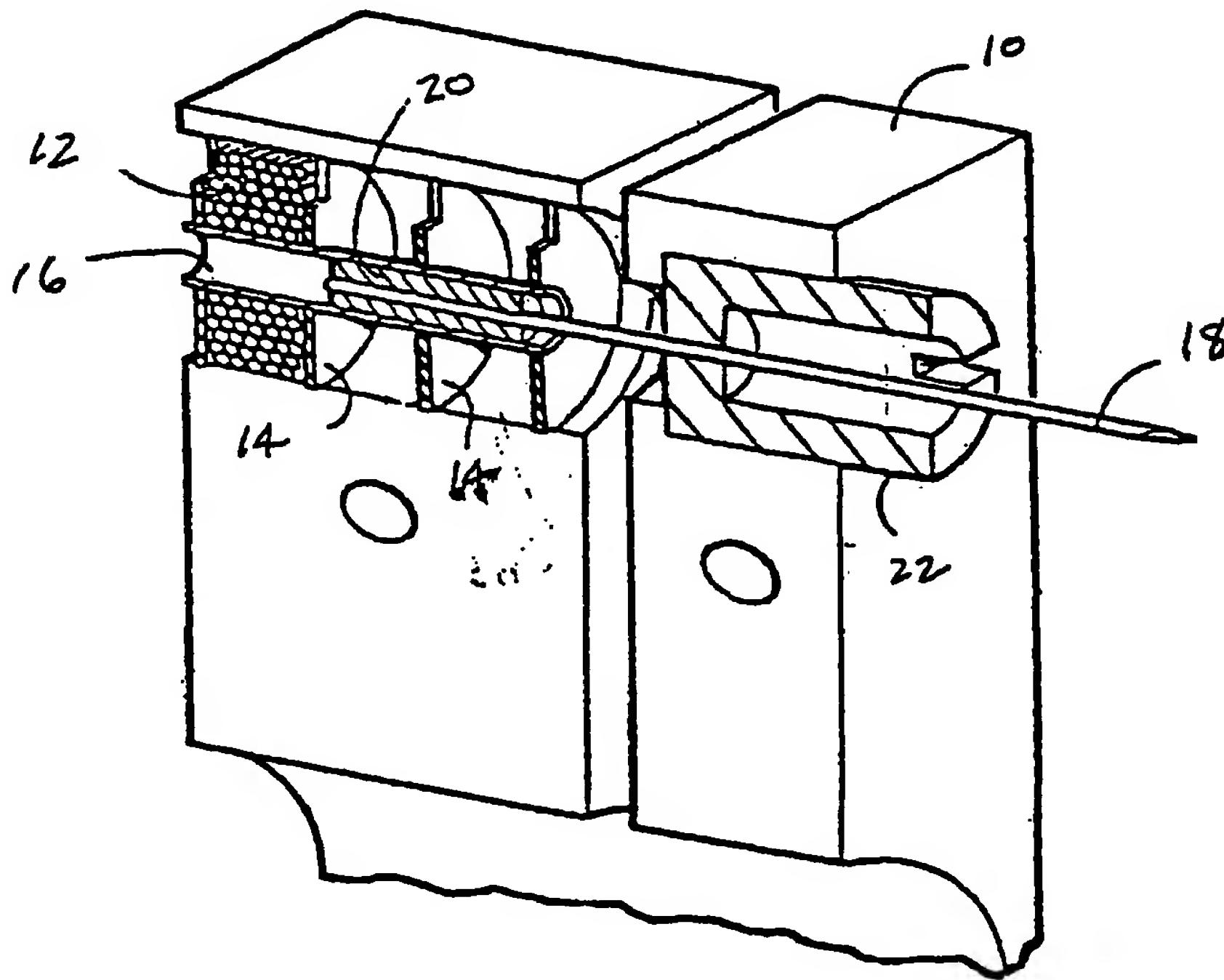
(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(71) Applicant (for all designated States except US): **PELIKAN TECHNOLOGIES, INC.** [US/US]; 1072 East Meadow Circle, Palo Alto, CA 94303 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO,

[Continued on next page]

(54) Title: METHOD AND APPARATUS FOR A FLUID SAMPLING DEVICE



(57) Abstract: Methods and apparatus are provided for manufacturing an analyte detecting device. In one embodiment, the apparatus comprises a housing; a penetrating member driver; a cartridge containing a plurality of penetrating members; a display on the cartridge; a linear slider on the housing, the slider coupled to a rod; and the rod moving with the slider, the rod having at least one roller. The device uses the linear motion of the slider to rotate the cartridge, punch open a new cavity and load a new penetrating member.

WO 2005/120365 A1



SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

METHOD AND APPARATUS FOR A FLUID SAMPLING DEVICE

5

BACKGROUND OF THE INVENTION

Technical Field:

The technical field relates to analyte detecting devices, and more specifically, device for obtaining a fluid sample.

Background Art:

10 Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor.

15 Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to 20 vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one 25 lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be “milked” from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

30 When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher types but on average it is

about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary.

Early methods of using test strips required a relatively substantial volume of blood to obtain an accurate glucose measurement. This large blood requirement made the monitoring experience a painful one for the user since the user may need to lance deeper than comfortable to obtain sufficient blood generation. Alternatively, if insufficient blood is spontaneously generated, the user may need to "milk" the wound to squeeze enough blood to the skin surface. Neither method is desirable as they take additional user effort and may be painful. The discomfort and inconvenience associated with such lancing events may deter a user from testing their blood glucose levels in a rigorous manner sufficient to control their diabetes.

A further impediment to patient compliance is the amount of time that at lower volumes, it becomes even more important that blood or other fluid sample be directed to a measurement device without being wasted or spilled along the way. Known devices do not effectively handle the low sample volumes in an efficient manner. Accordingly, improved sensing devices are desired to increase user compliance and reduce the hurdles associated with analyte measurement.

A further concern is the use of blood glucose monitoring devices in a professional setting. For the professional health care market, single device multiple user is the norm. A sterility barrier between patients is required or a single use professional lancing device is used and then discarded after use. To interface an integrated point of care lancing, sampling and analyte detection device with a multiple user paradigm, each lancet analyte detecting member pair may be isolated from the previous and subsequent user.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved apparatus for improving the release of penetrating members from their cartridges. The present invention also provided improved techniques for indexing and rotating the cartridge. At least some of these and other objectives described herein will be met by embodiments of the present invention.

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved apparatus for maintain sterility of a device being used on multiple users. The device described below functions to open the analyte detecting member channel and guide the sample into the analyte detecting member. It is then removed and discarded. Subsequent patient are protected as a new device is inserted to open the sensor at the time of lancing.. The present invention may also provide improved techniques for manufacturing such analyte detecting devices. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one embodiment of the present invention, the method comprises obtaining a fluid sample by: removing the protective covering from the packaging exposing a single item of sterile barrier film by pulling on the tab provided; pressing the sterile barrier film to the front and underside of the case; preparing a penetrating member by operating the slider on the side of the device and depressing the fire button once; pressing the center circular cutout in the foam front of the barrier film against the patients skin in the area to be lanced; lancing the patient; and checking that the outer case of device has not been contaminated by blood and if necessary clean it with disinfectant.

Methods and apparatus are provided for manufacturing an analyte detecting device. In one embodiment, the method comprises obtaining a fluid sample by: removing the protective covering from the packaging exposing a single item of sterile barrier film by pulling on the tab

provided; pressing the sterile barrier film to the front and underside of the case; preparing a penetrating member by operating the slider on the side of the device and depressing the fire button once; pressing the center circular cutout in the foam front of the barrier film against the patients skin in the area to be lanced; lancing the patient; and checking that the outer case of device has not been contaminated by blood and if necessary clean it with disinfectant.

5 In one embodiment of the present invention, a fluid sampling device is provided comprising a housing; a slider located on a surface of the housing, wherein the slider movable in a linear direction to rotate the cartridge to bring an unused penetrating member into position for use.

10 In one embodiment of the present invention, a fluid sampling device comprising a housing; a cartridge defining a plurality of cavities, the cartridge sized to fit within the housing; and a plurality of penetrating members at least partially contained in the cavities of the cartridge wherein the penetrating members are slidably movable to extend outward from the cartridge to penetrate tissue, the cavities each having a longitudinal opening providing access to an elongate portion of the penetrating member. The device may include a sterility barrier coupled to the cartridge, the sterility barrier covering a plurality of the longitudinal openings, wherein the sterility barrier covering the lateral openings is configured to be moved so that the elongate portion may be accessed by the gripper without touching the barrier; and a slider located on a surface of the housing, the slider movable in a linear direction to rotate the cartridge to bring an unused penetrating member into position for use. A tooth gear may be coupled to the slider to control a distance the slider can travel. A follower may be coupled to the slider. A cam surface may be engaged by the follower to lift the cartridge a desired distance above a first position to allow for rotation of the cartridge without engaging a gripper used to advance the penetrating member.

15 20 25 The cam surface may be aligned parallel to the slider. The linear motion of the cam rotates the cartridge and moves a plunger to break the sterility barrier on the cartridge. The cam surface comprise a linear strip of material with at least two raised portions and two depressed portions. The

30 In one embodiment of the present invention, a device is provided for use in penetrating tissue to obtain a body fluid sample. The device comprises a cartridge; and a plurality of penetrating members slidably coupled to the cartridge, each of the penetrating members having a distal end sufficiently sharp to pierce tissue and each of the penetrating members being moveable relative to the other ones of the penetrating members, so that the distal end of the respective

penetrating member is movable to penetrate tissue. Each of the penetrating members may be a bare lancet does not penetrate an outer sterility barrier during actuation.

In one embodiment of the present invention, a device may be provided comprising a cartridge having a plurality of cavities; and a plurality of penetrating members at least partially contained in the cavities of the single cartridge wherein the penetrating members are slidably movable to extend outward from lateral openings on the cartridge to penetrate tissue. A sterility barrier may be coupled to the cartridge, the sterility barrier covering a plurality of the lateral openings, wherein the sterility barrier covering the lateral openings is configured to be moved so that a penetrating member exits the lateral opening without contacting the barrier. The sterility barrier may cover the lateral openings and may be configured to be moved substantially vertically so that a penetrating member exits the lateral opening without contacting the barrier.

In one embodiment of the present invention, a device may be provided comprising a housing; a penetrating member driver; a cartridge containing a plurality of penetrating members; a display on the cartridge; and a linear slider on the housing, the slider coupled to a rod, wherein the rod moves with the slider, the rod having at least one roller. The device may use the linear motion of the slider to rotate the cartridge, punch open a new cavity and load a new penetrating member.

In one embodiment of the present invention, a method is provided for indexing. The method comprises moving a linear slider; the linear slider coupled to a rod; the rod moving with the slider, the rod having at least one roller; using the linear motion of the slider and linear motion of the rod to push at least one linear slider and to roll a roller along a linear cam surfaces to lift clear a drive assembly, rotate the cartridge, punch open a new cavity and load a new penetrating member.

In one embodiment of the present invention, a fluid sampling device is provided comprising a housing; a cartridge defining a plurality of cavities, the cartridge sized to fit within the housing; and a plurality of penetrating members at least partially contained in the cavities of the cartridge wherein the penetrating members are slidably movable to extend outward from the cartridge to penetrate tissue, the cavities each having a longitudinal opening providing access to an elongate portion of the penetrating member. A sterility barrier may be coupled to the cartridge, the sterility barrier covering a plurality of the longitudinal openings, wherein the sterility barrier covering the lateral openings is configured to be moved so that the elongate portion may be accessed by the gripper without touching the barrier; and a replaceable tissue interface barrier located on the housing, wherein the interface is replaced after each lancing event to prevent fluid contamination between different users.

Replaceable tissue interface may be positioned about an opening on the housing where the penetrating members extend outward to engage tissue on a user to obtain a fluid sample. Each of the cavities further include a lateral opening. Replaceable tissue interface may comprise a plurality of individually removable sheets of material, wherein one sheet is removed prior to 5 each lancing event to uncover a sterile unused sheet to provide an uncontaminated surface for the next user to use.

In one embodiment of the present invention, a device is provided for use in penetrating tissue to obtain a body fluid sample. The device comprises a cartridge; and a plurality of penetrating members slidably coupled to the cartridge, each of the penetrating members having a 10 distal end sufficiently sharp to pierce tissue and each of the penetrating members being moveable relative to the other ones of the penetrating members, so that the distal end of the respective penetrating member is movable to penetrate tissue; wherein each of the penetrating member is a bare lancet does not penetrate an outer, removable sterility barrier during actuation.

In one embodiment of the present invention, a device comprises a cartridge having a 15 plurality of cavities; and a plurality of penetrating members at least partially contained in the cavities of the single cartridge wherein the penetrating members are slidably movable to extend outward from lateral openings on the cartridge to penetrate tissue; a sterility barrier coupled to the cartridge, the sterility barrier covering a plurality of the lateral openings, wherein the sterility barrier covering the lateral openings is configured to be moved so that a penetrating member 20 exits the lateral opening without contacting the barrier. A fluid contamination barrier may be located on a housing using the device, the barrier being removed and replaced by a clean barrier prior to each lancing event.

In one embodiment of the present invention, a method is provided for obtaining a fluid 25 sample. The method comprises removing the protective covering from the packaging exposing a single item of sterile barrier film by pulling on the tab provided; pressing the sterile barrier film to the front and underside of the case; preparing a penetrating member by operating the slider on the side of the device and depressing the fire button once; pressing the center circular cutout in the foam front of the barrier film against the patients skin in the area to be lanced; lancing the patient; removing the barrier film from the front of the device; and checking that outer case of 30 device has not been contaminated by blood and if necessary clean it with disinfectant.

In one embodiment of the present invention, a method is provided for obtaining a fluid sample. The method comprises preparing the skin of the patient in the area to be lanced with a sterile wipe; removing the protective covering from the packaging exposing a single item of sterile barrier film by pulling on the tab provided; removing the sterile barrier film from the

carrier by pulling on the applicator tab provided; applying the adhesive side to the front area of the device ensuring that both the outer circular holes in the barrier film fit around the matching circular bosses on the front of the device; pressing the sterile barrier film to the front and underside of the case taking care not to touch the firing area of the barrier film; preparing a 5 penetrating member by operating the slider on the side of the device and depressing the fire button once; pressing the center circular cutout in the foam front of the barrier film against the patients skin in the area to be lanced; lancing the patient by depressing the fire button a second time; removing the device from the patients skin and take the blood sample from their skin; removing the barrier film from the front of the device using the tab provided and dispose of it 10 properly; and checking that outer case of device has not been contaminated by blood and if necessary clean it with disinfectant.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

15

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an embodiment of a controllable force driver in the form of a cylindrical electric penetrating member driver using a coiled solenoid -type configuration.

Figure 2A illustrates a displacement over time profile of a penetrating member driven by a harmonic spring/mass system.

20 Figure 2B illustrates the velocity over time profile of a penetrating member driver by a harmonic spring/mass system.

Figure 2C illustrates a displacement over time profile of an embodiment of a controllable force driver.

25 Figure 2D illustrates a velocity over time profile of an embodiment of a controllable force driver.

Figure 3 is a diagrammatic view illustrating a controlled feed-back loop.

Figure 4 is a perspective view of a tissue penetration device having features of the invention.

30 Figure 5 is an elevation view in partial longitudinal section of the tissue penetration device of Figure 4.

Figure 6 shows an exploded perspective view of one embodiment of a device according to the present invention.

Figure 7 shows a cross-sectional view of one embodiment of a punch according to the present invention.

Figure 8 shows another embodiment of a punch according to the present invention.

Figure 9 shows one embodiment of a gripper with a shield.

Figures 10-12 show other embodiments of a gripper.

Figures 13-14 show embodiments of a gripper and a drive assembly.

5 Figures 15-16 show a cross-section and side view of one embodiment of the gripper and the drive assembly.

Figure 17 shows a schematic of one embodiment of a slider used to rotate a disc.

Figures 18 through 21 are cut-away views of various elements of a device according to the present invention.

10 Figures 22-23 show embodiments of an analyte testing device for use with a test strip.

Figures 24-28 show various embodiments of a tissue interface.

Figure 29 shows one embodiment analyte testing strip dispenser.

Figure 30 through 35 shows various views of embodiments of a barrier according to the present invention.

15 Figures 36 through 40 show various close-up views of areas of the barrier.

Figure 41 shows one embodiment of packaging for use with a barrier according to the present invention.

Figure 42 shows a view of one portion of a cartridge for use with the present invention.

20 DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving release of penetrating members for a cartridge. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following 30 detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein

are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

5 “Optional” or “optionally” means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures

10 wherein the analysis feature is not present.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the 25 driver coil pack with a first coil 12 flanked by iron spacers 14 which concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current 30 between the first coil 12, the middle coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available lancet devices, once the launch is initiated, the stored energy determines the 5 velocity profile until the energy is dissipated. Controlling impact, retraction velocity, and dwell time of the penetrating member within the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in 10 skin deformation from patient to patient based on skin hydration.

In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is illustrated in Figure. 2C 15 which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a lancet, into tissue. 20 Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired 25 circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has 30 chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the embodiments above and may be found

in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may select a 200 micron diameter penetrating member to achieve these results. For each class of lancet, both diameter and lancet tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft 84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The penetrating member shaft 201 may be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3 to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of

the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor embodiments could be used, provided they possess the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90 degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidably accept the

proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

Referring now to Figure 6, a still further embodiment of a cartridge according to the present invention will be described. Figure 6 shows one embodiment of a cartridge 300 which may be removably inserted into an apparatus for driving penetrating members to pierce skin or tissue. The cartridge 300 has a plurality of penetrating members 302 that may be individually or otherwise selectively actuated so that the penetrating members 302 may extend outward from the cartridge, as indicated by arrow 304, to penetrate tissue. In the present embodiment, the cartridge 300 may be based on a flat disc with a number of penetrating members such as, but in no way limited to, (25, 50, 75, 100, ...) arranged radially on the disc or cartridge 800. It should be understood that although the cartridge 300 is shown as a disc or a disc-shaped housing, other shapes or configurations of the cartridge may also work without departing from the spirit of the present invention of placing a plurality of penetrating members to be engaged, singly or in some combination, by a penetrating member driver.

Each penetrating member 302 may be contained in a cavity 306 in the cartridge 300 with the penetrating member's sharpened end facing radially outward and may be in the same plane as that of the cartridge. The cavity 306 may be molded, pressed, forged, or otherwise formed in the cartridge. Although not limited in this manner, the ends of the cavities 306 may be divided into individual fingers (such as one for each cavity) on the outer periphery of the disc. The particular shape of each cavity 306 may be designed to suit the size or shape of the penetrating member therein or the amount of space desired for placement of the analyte detecting members 808. For example and not limitation, the cavity 306 may have a V-shaped cross-section, a U-shaped cross-section, C-shaped cross-section, a multi-level cross section or the other cross-sections. The opening 810 through which a penetrating member 302 may exit to penetrate tissue may also have a variety of shapes, such as but not limited to, a circular opening, a square or rectangular opening, a U-shaped opening, a narrow opening that only allows the penetrating member to pass, an opening with more clearance on the sides, a slit, a configuration as shown in Figure 75, or the other shapes.

In this embodiment, after actuation, the penetrating member 302 is returned into the cartridge and may be held within the cartridge 300 in a manner so that it is not able to be used again. By way of example and not limitation, a used penetrating member may be returned into the cartridge and held by the launcher in position until the next lancing event. At the time of the next lancing, the launcher may disengage the used penetrating member with the cartridge 300 turned or indexed to the next clean penetrating member such that the cavity holding the used

penetrating member is positioned so that it is not accessible to the user (i.e. turn away from a penetrating member exit opening). In some embodiments, the tip of a used penetrating member may be driven into a protective stop that holds the penetrating member in place after use. The cartridge 300 is replaceable with a new cartridge 300 once all the penetrating members have been used or at such other time or condition as deemed desirable by the user.

Referring still to the embodiment in Figure 6, the cartridge 300 may provide sterile environments for penetrating members via seals, foils, covers, polymeric, or similar materials used to seal the cavities and provide enclosed areas for the penetrating members to rest in. In the present embodiment, a foil or seal layer 320 is applied to one surface of the cartridge 300. The seal layer 320 may be made of a variety of materials such as a metallic foil or other seal materials and may be of a tensile strength and other quality that may provide a sealed, sterile environment until the seal layer 320 is penetrated by a suitable or penetrating device providing a preselected or selected amount of force to open the sealed, sterile environment. Each cavity 306 may be individually sealed with a layer 320 in a manner such that the opening of one cavity does not interfere with the sterility in an adjacent or other cavity in the cartridge 800. As seen in the embodiment of Figure 6, the seal layer 320 may be a planar material that is adhered to a top surface of the cartridge 800.

Depending on the orientation of the cartridge 300 in the penetrating member driver apparatus, the seal layer 320 may be on the top surface, side surface, bottom surface, or other positioned surface. For ease of illustration and discussion of the embodiment of Figure 6, the layer 320 is placed on a top surface of the cartridge 800. The cavities 306 holding the penetrating members 302 are sealed on by the foil layer 320 and thus create the sterile environments for the penetrating members. The foil layer 320 may seal a plurality of cavities 306 or only a select number of cavities as desired.

In a still further feature of Figure 6, the cartridge 300 may optionally include a plurality of analyte detecting members 308 on a substrate 822 which may be attached to a bottom surface of the cartridge 300. The substrate may be made of a material such as, but not limited to, a polymer, a foil, or other material suitable for attaching to a cartridge and holding the analyte detecting members 308. As seen in Figure 6, the substrate 322 may hold a plurality of analyte detecting members, such as but not limited to, about 10-50, 50-100, or other combinations of analyte detecting members. This facilitates the assembly and integration of analyte detecting members 308 with cartridge 300. These analyte detecting members 308 may enable an integrated body fluid sampling system where the penetrating members 302 create a wound tract in a target tissue, which expresses body fluid that flows into the cartridge for analyte detection by

at least one of the analyte detecting members 308. The substrate 322 may contain any number of analyte detecting members 308 suitable for detecting analytes in cartridge having a plurality of cavities 306. In one embodiment, many analyte detecting members 308 may be printed onto a single substrate 322 which is then adhered to the cartridge to facilitate manufacturing and 5 simplify assembly. The analyte detecting members 308 may be electrochemical in nature. The analyte detecting members 308 may further contain enzymes, dyes, or other detectors which react when exposed to the desired analyte. Additionally, the analyte detecting members 308 may comprise of clear optical windows that allow light to pass into the body fluid for analyte analysis. The number, location, and type of analyte detecting member 308 may be varied as 10 desired, based in part on the design of the cartridge, number of analytes to be measured, the need for analyte detecting member calibration, and the sensitivity of the analyte detecting members. If the cartridge 300 uses an analyte detecting member arrangement where the analyte detecting members are on a substrate attached to the bottom of the cartridge, there may be through holes (as shown in Figure 76), wicking elements, capillary tube or other devices on the cartridge 300 to 15 allow body fluid to flow from the cartridge to the analyte detecting members 308 for analysis. In other configurations, the analyte detecting members 308 may be printed, formed, or otherwise located directly in the cavities housing the penetrating members 302 or areas on the cartridge surface that receive blood after lancing.

The use of the seal layer 320 and substrate or analyte detecting member layer 822 may 20 facilitate the manufacture of these cartridges 10. For example, a single seal layer 320 may be adhered, attached, or otherwise coupled to the cartridge 300 as indicated by arrows 324 to seal many of the cavities 306 at one time. A sheet 322 of analyte detecting members may also be adhered, attached, or otherwise coupled to the cartridge 300 as indicated by arrows 325 to provide many analyte detecting members on the cartridge at one time. During manufacturing of 25 one embodiment of the present invention, the cartridge 300 may be loaded with penetrating members 302, sealed with layer 320 and a temporary layer (not shown) on the bottom where substrate 322 would later go, to provide a sealed environment for the penetrating members. This assembly with the temporary bottom layer is then taken to be sterilized. After sterilization, the assembly is taken to a clean room (or it may already be in a clean room or equivalent 30 environment) where the temporary bottom layer is removed and the substrate 322 with analyte detecting members is coupled to the cartridge as shown in Figure 6. This process allows for the sterile assembly of the cartridge with the penetrating members 302 using processes and/or temperatures that may degrade the accuracy or functionality of the analyte detecting members on substrate 322. As a nonlimiting example, the entire cartridge 300 may then be placed in a further

sealed container such as a pouch, bag, plastic molded container, etc...to facilitate contact, improve ruggedness, and/or allow for easier handling.

In some embodiments, more than one seal layer 320 may be used to seal the cavities 306. As examples of some embodiments, multiple layers may be placed over each cavity 306, half or some selected portion of the cavities may be sealed with one layer with the other half or selected portion of the cavities sealed with another sheet or layer, different shaped cavities may use different seal layer, or the like. The seal layer 320 may have different physical properties, such as those covering the penetrating members 302 near the end of the cartridge may have a different color such as red to indicate to the user (if visually inspectable) that the user is down to say 10, 5, or other number of penetrating members before the cartridge should be changed out.

Referring now to Figures 7 and 8, various embodiments of the present invention will now be described in further detail. Improvements have been made to the punch device 400. The present invention addresses issues with the punch moving the cut foil to the sides of the chamber, so that the foil springs back and you get some end effects where the punch angles the foil into the corner, resulting in tearing rather than a clean cut to open the sterility barrier. The gripper has to bend the foil out of the way, as it runs along the channel and this results in the half Newton range or force required.

Figure 7 shows an embodiment of the punch 400 with a widened portion 402 that tightly fits against the opening of the cavity. Some embodiments may also have a flash portion 406 that interferes with the punch 400 during punching. The helps push the flaps of the foil to the side and does not interfere with the gripper during travel.

Figure 8 shows yet another embodiment with a narrow punch 410 with winged portions 412. The wings 412 are of sufficient size and stiffness to push the foil pieces against the side of the cavities.

Referring now to Figures 9 through 16, a still further embodiment of the present invention describes a shield or guide rail attached to the gripper and not the punch. Thus the shield is in placed while the gripper is coupled to the penetrating member. It does not need to be fitted to be exactly the same size as the cavity width, such as may be needed by a punch, thus allowing for easier manufacturability.

Referring now to Figures 9 and 10, in this embodiment the shield 430 is mounted above the gripper 432. This hollow open channel rides over the gripper and is fixed to the track. It also guards from accidentally touching the gripper itself. The present invention uses the guard to bend the foil out of the way.

Referring now to Figure 11, a view of the gripper 432 engaged to a penetrating member and a shield 430 pushing foil aside is shown. Figure 12 shows yet another cross-section of the gripper 432 and shield 430. Figures 13 and 14 shows yet another depiction with the entire gripper and drive assembly positioned over a cartridge 440 containing a plurality of penetrating members.

Figure 15 shows a cross-section view with the entire gripper and drive assembly positioned over a cartridge 440 containing a plurality of penetrating members 442. Figure 16 shows a perspective view of just the gripper and drive assembly.

In yet another embodiment of the present invention, there is now a new type of punch proposed which will result in less friction and may be able to avoid a razor sharp blade and use a blunt blade instead. This punch has an "H" blade leaving an "H" cut which the guard now can fold nicely out of the way. The blade may be angled like a guillotine with feet at either end to reduce the force needed to cut open the foil and hence we could maybe increase the foil thickness (we are at 12 microns and would like to be at 20 to avoid pinholes (and hence bacteria/spores))

In a still further embodiment, the present invention may include an improved armature design. In one embodiment, the armature is made stiffer, by increasing diameter of the rod or going to a rectangular cross section in the place that suffers the most deflection. Bearings can also be modified (in the cartridge); currently it is a round lancet in a square bearing. The plan is to set the lancet in a "V" channel and then to provide a light downward force pressing the lancet into the "V". As the lancet wants to move due to the asymmetrical chamfer, that force will be overcome and then it can move in compliance with the chamfer force. We apply this force to the top of the gripper using a "V" shape top on the gripper, the gripper is now stabilized so that it can't rattle around, while maintaining the compliance for the lancet to move because of the chamfer. The end result is dampening of the oscillations in the armature, thus reducing the jitter.

Space: to reduce the length of the travel of the slider due to space constraints. One solution would be to ramp quickly and ramp up only when needed, therefore it becomes a non-linear cam arrangement. This gets us reduced length. In addition, it allows us to shorten the stroke. To get height for PCB we can go from a double-sided cam to a single sided cam with a spring to provide the force in two directions.

Referring now to Figure 17, yet another aspect of the present invention will now be described. To bring a new, unused penetrating member to use, the cartridge 500 may be rotated as indicated by arrow 502. A linear slider 510 moves forward and backward as indicated by arrow 512. The forward motion of the slider 510 rotates the cartridge, among other things. In

some embodiments, backward motion may be used to rotate the cartridge (it all depends on where the slider starts). Rotation occurs when a keyed gear (not shown) that the opening 514 fits over is rotated by motion of the slider 510. Of course, the slider 510 in the present embodiment also actuates a plurality of other motions such as clearing the gripper, shield, and drive assembly, to lift them clear so that the cartridge 500 can rotate.

Referring now to Figure 18 shows how movement of the slider 510 moves rod 520 as indicated by arrows 522. For ease of illustration, certain portions of the device are removed to allow easier visualization of the moving parts. The motion of rod 522 causes a second slider 530 to move as indicated by arrow 532 and engage a stub 534 on the rotating wheel 540. This wheel 540 turns the gear the fits inside the opening 514, which rotates the cartridge. In the present embodiment, a roller 550 also travels on a cam surface 552.

As seen in Figure 19, the roller 550 also move a slider 560. The rod 520 also includes yet another roller 562. This roller as seen in Figure 20, follows another cam surface 570. The cam surfaces 552 (Figure 18) and 570 (Figure 20) allow for raising and lowering of the punch, shield, gripper, drive assembly, etc...to allow for the cartridge to rotate and a new penetrating member cavity to be opened and a member loaded for firing. In some embodiments, the various steps that need to happen are similar to those described in commonly assigned copending U.S. Patent Application. Ser. No. _____ (38187-2607) filed December 18, 2002.

Figure 21 shows still further embodiments of the present invention. It more clearly shows some of the elements such as roller 562. Embodiments using the linear motion of the slider 510 and linear motion of the rod 520 pushing linear sliders and pushing rollers to follow linear cam surfaces are very robust and will not easily fail. It should be understood that in some embodiments, a motor may be coupled to the slider to advance it instead of relying on user force.

Referring now to still further embodiments of the present invention:

1. C Shaped slug 3.6 mm – increase force outer diameter bigger, flux lines shorter saturates later so more force.

2. Ratchet finger: forces the punch cycle, removes peg pivot and spring mechanism for the one-way action before return cycle is initiated. For D layout flexible finger which is S shaped – the S shape give the spring like action without the need for and extra spring. 6 parts to 2. Delete a coil spring and pins to hold it. It is small but injection moldable, pins are molded in.

4. Hinge on the gripper track: Attach the solenoid to the gripper track so that the whole lot moves when the pull the gripper off the lancet. This is pivoted by bending so that the coil moves (and flag) but on the sensor just the flag in the slot.

5. Warping of disc: if the disc is over indexed (error) and rotational error in the gripper track then the shields will not be perfectly aligned. The main pockets are now tapered to take care of this. The walls are now parallel (they were tapered before).. Tapering allows the shields to only touch in the back corner. This is being tested this week and may reduce the forces to push in and pull out (the fact that it is tapered. If the disc isn't flat downwards, the gripper can move down to follow the tract of the resilient to cartridge. Statically determinant eg three legged stool on uneven floor. Takes into account poor manufacture in all parts including the gripper arm as well as the consumable. Consistent friction with any changes that might occur due to manufacturing. This is another advantage of the bearing system.

20 6. Collapsing cam mechanisms: ADA model – rolling beam slider needs mechanism so that it rolls back it punches but does not already punch the next cavity. Is a ratchet ball point pen mechanism. Slot and wheel of ADA is too thick. New one has metal component which latches in place, pushing punch down, pushes component backwards, so that hump disappears. The is called the return plate. (sliding plate was Dons idea, they added metal)

25 7. Punch force detection is also in this model

8. Capacitive sensing: 2 embodiments, electrically connected to needle – since we have metal gripper and have an electrical circuit (they have model for needle sensing touching finger. Embodiment 2 pouching is now repeated deals with pouching only.

30 9. Leak testing :hermetic seal check on each pocket – desiccate, dye. Cavities fill with ink – end up with depression in the foil over the cavity – its this depression they have not observed in combination with the dye test. Foil thickness has not been determined, 11 or 20 microns are the two candidates. 20 might be too high for punch, it's the same though, pin holes were less. If punch force stays low they will probably go for the twenty micron. Dye increase can sense 10 um and cibi test was less than 5 um.

10. Gripper stripper II chunk of plastic runs on track and pulls the gripper off the lancet. Does the same as the old cam but it is in two parts at it is a thinner embodiment.

11. Plastic punches – swallowtail punch shape. Front punch the cutting edge I creating a T shape. Back punch is hourglass shaped. Doing every other one and going around 5 twice. Main punch is wider at front on the back because chambers are now tapered. The edges at the center are the cutting; gabled ends act as shearing guillotine. Saggy roof (swallowtail), minimized the peak force over all the displacement, saggy roof achieves this.

12. This is D layout, cartridge is Saturn 31 aka Rev 5 Disc 08000009-2. Design features added to solve jitter and friction. Jitter spec 50 microns, friction in the armature (moving 10 assembly). Predictable repeatable is better than none or high friction. Changed the bearing system (armature) slug has carbon rod and sits in tube. The end of the rod has a molding and the gripper. Lancet sits in cartridge and has two bearings, stroke is between the two bearings. The bearings are now V shaped light force makes lancet sit in v, when it hits skin it can ride up the sides of the v when the lancet hits the skin. It moves due to the 3 facet tip. This also allows a wide 15 clearance. Before the result was jitter, the v groove defines the position and clearance in 98 microns. Free flight free flight is zero because it is getting pushed into the v. Can now move left, right or twist and follow the tip into the skin, The clearance at the rear and front are calculated to account for the orientation of the lancet into the skin it is free to move. The gripper is now mounted on a hinge and can rotate with the lancet. Plastic has elastic properties (delryn acetyl) is 20 used for all springy parts in the model. The gripper head is what rotates, not the gripper, so molding is compliant to attach the gripper to the shaft. Slug is now diamond shaped. The damper sits on the rod and pushes down and applies the down wards pressure and damps out oscillation in the rod. This takes some juice from the coil. 15 mN frictional force. Jitter plotted against friction force. It's below the 15 micron spec at 15 mN force at which contact point can be measured. Jitter 25 under control by using friction A component sets the friction so that it is reproducible, so control system can compensate. There is some penalty in battery life – this has to be determined. This is the new Bearing system. Gripper then gets locked and then damper doesn't function while in the parked position. The gripper track – the shield are pushed out of the way. They fold the slits out of the way. Shield can maybe be used to keep the foil out of the way.

Referring now to Figure 22, another embodiment of the present invention will now be described in greater detail. The device 1400 includes a cartridge similar to that of Figure 6, except that it only has penetrating members, no analyte sensing. In this embodiment, the device 1400 include a glucose or other analyte meter. A test strip 1410 may be inserted into a slot on the device 1400 to allow for the body fluid on the test strip to be analyzed. As seen in Figure 22, in different embodiments, the slot for the strip 1410 may be inserted in a variety of locations (as indicated in phantom). In some embodiments, the electronic lancing device 1400 may also dispense the test strips from a cartridge or cassette held within the housing of the device 1400. The electronic lancing device may use a radial cartridge for housing the penetrating member or a bandolier type design as set forth in commonly assigned, copending U.S. Patent Application Ser. No. _____ (38187-2551) or PCT application No. _____ (38187-2721).

Referring now to Figure 23, a still further embodiment is shown where an attachment 1420 may be added to an electronic lancing device. This attachment, in one embodiment, contains a plurality of test strips for dispensing. In another embodiment, it may provide the electronics used for functioning as glucose or other analyte meter.

Referring now to Figures 24 through 28, these embodiments of the present invention relate to Point of Care lancing, sampling, sensing, and disposable. The present invention provides a single device, suitable for use with multiple users in situations such as POC applications in adults or neonates. In one embodiment, the present invention address the issue by having a removable front end that both functions as a sample acquisition device and a sterility barrier between uses of a single device with multiple users in a professional care environment.

Referring now to Figures 24 and 25, sample capture from the surface of the finger may be carried out after the lancing step. A shield or guard may protect the front end from contamination and transfer of biohazard between successive patients. Figure 24 shows that a portion 1422 may be hydrophobic. Figure 25 shows that there may be hydrophobic plate 1412 and a hydrophilic mesh 1414.

Referring now to Figure 26, the present invention is a device 1425 that has a plastic molded part with “tentacles” 1430 designed to remove the foil covering of the analyte detecting member at the time the test is taking place. Figure 27 shows some sizing of opening on the housing. The plug may snap into the aperture of the front end. It protects back plate and front end from blood. Clips also remove packaging. Figure 28 shows a perspective view of a fluid sampling device having a plurality of front ends 1425 on the device that are ready for use. Figure 28 shows that old or used front ends 1427 and new front ends 1429 may be placed on the

housing. By way of example and not limitation, they may be mounted on band on a back portion of the housing.

Two embodiments of the sampling paradigm are possible.

(1) The lancing is carried out in a separate operation and the surface of the finger is touched to the wicking or sip-in treated front end of the disposable "limpet" 1425. Blood is guided into the analyte detecting member channel and the test is carried out. Post testing the "limpet" front end 1425 is removed and the disk indexed before inserting the next "limpet" for the next diagnostic test. The sample acquisition channel of the limpet can be configured with mesh to guide the sample to the analyte detecting member or hydrophilically treated to guide the blood to the analyte detecting member. Since POC tests require higher amounts of blood volume the dead space for the priming of the channel leading to the not considered limiting. Limpets can be stored on board in the instrument and dispensed as a cassette. They can also be disposed of in the same cassette as used and then the entire cassette thrown way at the end of 25 or 50 patients have been tested.

(2) Embodiment two would allow an fluid device combined with analyte detecting members on a disk. The punch mechanism of the lancing device can open the seal. The function of the limpet would them be to attach and for a sterility barrier on the front end, allow passage of the penetrating member through the center and perhaps contain surface treatment or mesh to guide the sample into the analyte detecting member chamber. The limpet can be configured to prevent contamination in a side-to-side aspect between analyte detecting members by forming a physical barrier between adjacent analyte detecting members. It can be configured to prevent splatter of blood on the back plane (inside of the front end) of the instrument. It may also function as a finger positioning device as it can be contoured and shaped without affecting the front face of the instrument.

Referring now to Figure 29, these embodiments of the present invention relate to lancing, sampling, sensing, disposable, and manufacture. In one embodiment, It is an integrated sampling / glucose-sensing system. The present invention may integrate multiple lancings with multiple electrochemical glucose sensing events. It is solved here, in some embodiments, in a very simple way by integrating the functions without integrating the two different activities (lancing and sensing) in the same physical device.

Referring again to Figure 29, one particular simple integration of the functions of blood sampling and glucose-sensing is shown. In this embodiment, a small package of disposable glucose sensing strips 1500 in a dispenser 1508 is physically adjoined to the lancing device. In order to perform a glucose analysis, a user tears off / peels off a strip from the dispenser, sticks it

to the front end of the lancing device (using suitable registration features on both the strip and the front end), and then uses the device to lance and obtain blood. The strip 1500 has many of the blood collection features, notably a woven lollipop structure to guide blood over an electrochemical glucose analyte detecting member which is an integral part of the strip (the strip 5 is very similar in function to any glucose test strip). The front end of the lancing device may have electrode contacts which can either actively or passively make contact with the electrochemical “signal out” pads of the strip. In a particular embodiment of this concept, a hinged door be deployed from the lancing device front end to aid in registering the glucose strip and to make contact with the “signal out” pads. Following use, the disposable glucose strip is 10 removed from the front end of the device and disposed of in the normal way.

A somewhat similar, but more integrated, approach is discussed. Here the glucose-sensing strips are still kept physically separate from the multi-lancing elements, and are only functionally integrated, but in this embodiment, the glucose-sensing strips are integrated into their own multi-strip roll. Using this multi-strip roll (in a cartridge very similar to an old 110 film canister), the indexing of the penetrating member launcher can be used to move forward new, glucose strips. The glucose strips in their roll move across the front end of the fluid sampling device, and perform similarly to the strips in the concept above. The strips have registration features corresponding to registration features on the front end, and they have blood acquisition means, like a woven lollipop structure, to guide blood from the finger-lancing site to the electrochemical analyte detecting members. Contact to the “signal out” pads of the glucose test strips are accomplished by electrode contacts integral to the front end of the fluid sampling device. But in this case, there are no individual strips either to put on the front end of the fluid sampling, or to remove from the front end after use. The strips are deployed from a film canister-type cartridge, and are rolled back up into a similar canister feature on the other side of 15 the fluid sampling after use. It is clear that a multi-strip canister of this sort could be functionally integrated with a multiple penetrating member system of various forms. A multiple-strip canister may be functionally integrated with multiple penetrating members in the form of a penetrating member magazine, or a radial penetrating member cartridge.

Referring now to Figure 30, still further embodiments of the present invention will be 30 discussed. The technical field of these inventions relate to lancing, blood acquisition, contamination avoidance, sterile disposable materials. Most systems for gaining access to blood are single-use devices. Systems that are used to gain access to the blood of multiple people have the burden of showing that blood cannot be carried from one user to another. A means for avoiding that “blood carry-over” is the subject of this invention. That means is basically a

specific material and design of tape that is used, and then discarded after use, between each patient.

Referring now to Figure 30, one embodiment of a sterile disposable adhesive blood barrier 1600 is to be placed between the device and the patient. The barrier 1600 may be applied to the exterior surface of the device before use with each patient and disposed of immediately after use. In the present embodiment, the adhesive blood barrier 1600 prevents contamination of any part of the device that may act as a pathway for transmission of pathogens between patients. Illustrations of the design are shown in Figure 30 shows the barrier by itself. Figure 31 shows the barrier 1600 attached to a fluid sampling device 1400. The barrier 1600 may have a bend relief 1610, foam offset 1612 and location features 1614 to help position the barrier properly. The port 1616 is where a penetrating member exits to piece tissue.

1.1. Description of Operation

As seen in Figure 31, the user will apply the sterile adhesive blood barrier 1600 with foam pad to the front of the device and then place the patients' fingertip or other skin surface against the high-density foam offset pad in the firing area. The foam offset pad 1612 serves to maintain a small air gap between the patients' finger and the blood barrier film. The penetrating member then is fired through the sterile adhesive blood barrier 1600 and enters the patient before retracting back into the cartridge. Testing described below has shown that the small hole created by the penetrating member, in combination with the air gap created by the foam, is highly resistant to fluid flow. The blood barrier 1600 acts effectively in preventing transfer of blood to the device despite the presence of such a hole.

In one embodiment, the selected film for the barrier 1600 is manufactured by 3M Medical Tapes and Adhesives under the catalog name "3M™ Tan 5 mil Polyethylene Medical Tape 1523, 63# Liner".

The selected foam is sold by Scapa Medical UK under the catalog name "Medifix 4005/868 Single Coated Medical Pressure Sensitive Polyurethane Foam". The offset pad is made up to the required thickness as a multi-layer laminate.

Figure 32 is a cross-sectional diagram shows the relative dimensions of the proposed system prior to firing.

Figures 33, 34, and 35 are three diagrams that illustrate each phase of the lancing operation.

1.2. Prevention of Blood Transfer

First and foremost the film and foam prevent blood being left on the casework of the device by being a simple physical barrier. In one embodiment, the blood barrier 1600 will cover

nearly the entire front of the device and also wrap underneath the device. User instructions require that the user clean any obvious blood contamination that is spread outside the area of the barrier with a suitable disinfectant method.

The chief risk is that the blood will be transmitted to the device via the hole created in the barrier film by the lancing operation. The success of the design relies on the elasticity of the selected film closing the hole, the surface tension and viscosity of the blood making passage through the small hole difficult, and the air gap providing for an alternative route in which the blood pressure can be released avoiding a pressure difference across the film.

Several experiments were completed to select a film and confirm that it satisfied the requirement of preventing contamination of the device.

1.2.1. Hydrostatic pressure test

Objective: To test whether a suitable film and air gap could withstand a blood pressure equal to that in the capillary blood vessels of the patient after being pierced by a penetrating member.

Method: A length of tubing filled with water was capped at one end by a piece of film intended to simulate skin. Offset from this "skin" was a sample of the film being tested. The height of the free surface of water was set to the maximum pressure likely to be transmitted to the film by the capillary bed, approximately 45 cmH₂O (see below). A penetrating member was pushed through the test film and the "skin" and then slowly withdrawn whilst backlit and being filmed by a high speed macro video camera. This process was repeated for a variety of films of differing material and thickness.

Results: In the video footage it is obvious which combinations of air gap and film prevent fluid transmission. Results are presented in Table 1 and it is shown that the selected film will prevent fluid transmission for pressures of at least 45 cmH₂O when offset from the skin by 0.6mm.

Test	Film	Description	Nature of film	Pressure (cmH ₂ O)	Air Gap (mm)	Penetration (Yes/No)
1	6016/877	40um PU	Hydrophilic	9	0	N
2			and elastic	10	0	N
3				12.5	0	Y
4				16	0	Y
5	Bioflex 140	25um PU	Hydrophilic	10	0	N
6			and elastic	10.5	0	Y

7	RX941PLT	40um PET	Hydrophobic	10	0.6	N
8			and inelastic	16	0.6	Y
9	1523	130um PE	Hydrophobic	20	0	Y
10			and elastic	25	0.6	N
11				30	0.6	N
12				32	0.6	N
13				45	0.6	N
14				45	0.6	N

The video footage shows the elastic closure of the hole as the penetrating member is retracted. This closure reduces the area of the hole to a fraction of the penetrating member diameter increasing the resistance to fluid flow tremendously.

5 The elastic closure also prevents the penetrating member carrying with it large drops of blood to the device side of the barrier which might otherwise be dislodged before the penetrating member is parked safely in the cartridge. As the penetrating member retracts, the film closes around it, wiping off any blood. Very small amounts of blood that may adhere to the surface of the penetrating member and be carried back to the device side of the barrier will be contained
10 within the penetrating member cavity.

1.2.2. Theoretical calculation

Theory governing fluid passage through a small hole states that the required driving pressure for liquid to move through a small hole is given by:

$$\text{Equation 1} \quad P = \frac{4a}{d}$$

15 where : P is the driving pressure in Pa
 a is the surface tension of the fluid in N/m
and d is the diameter of the hole in meters

The surface tension of blood has been shown to be in the region of 56×10^{-3} N/m. The
20 crescent shaped hole left by the penetrating member after elastic closure is approximately 6×10^{-9} m² in area (see "Figure 36. Puncture hole with 0.317mm diameter penetrating member for scale"), which is equivalent to hole with a diameter of 4.4×10^{-5} m. Equation 1 therefore gives a required driving pressure of 5.10 kPa. Adhesion of the blood to the sharp corners of the hole is likely to make the actual required driving pressure significantly higher than this

The blood pressure in the capillary bed drops from a maximum of 30-35 mmHg at the arterial end to 12-15 mmHg at the venous end. A pressure of 30-35 mmHg equates to approximately 4.65 kPa or 45 cm H₂O. The actual pressure witnessed by the barrier and hole is likely to be significantly lower than this due to the presence of the air gap and the resistance to flow through the outer epidermis.

5 Theory therefore predicts that because the actual driving pressure is less than that required, fluid flow will not occur.

1.2.3. In vivo test

10 Objective: To confirm the laboratory experimentation the film selection by in vivo testing using a prototype device and live patient.

Method: The barrier film and foam offset pad were applied to the prototype device. The device was then placed against the finger of the patient and fired. The barrier was inspected on the Mitutoyo after the lancing operation at 96 X magnification.

15 Result: The barrier film showed no transmission of blood. During this testing it was also shown that the blood is not smeared on the blood barrier and that a sufficient sample of blood is left on the patient skin for analytical testing.

Figure 37 shows a fluid sampling device with finger; Figure 38 shows a blood drop on patient side of film (16 X); Figure 39 shows device side of film after firing into finger (96 X).

20 The laboratory tests and theoretical equations support the hypothesis that the design is effective in preventing contamination of the device by blood.

1.3. Foreign Body Implantation

It is desirable that the penetrating member does not carry material from the adhesive blood barrier with it and implant it into the patient. The film is an elastic and ductile material being punctured by a sharpened point and it is therefore highly unlikely that pieces will be separated off and carried with the lubricated penetrating member tip. The following inspections were carried out to confirm this.

25 Method: A digital photograph of the penetrating member was taken immediately after firing through the adhesive film. This inspection was made along the length of 10 penetrating members after firing through the adhesive film.

30 The film was inspected after firing through it.

A high frame-rate (2000 frames/second) digital video was taken of the lancing operation from the patient side.

Results: No plastic material or adhesive was seen stuck to the penetrating member.

Inspection of the film using the Mitutoyo after piercing did not suggest that material had been removed (see “Figure 25. Barrier film after puncture (96X magnification)”).

No material removal was seen in the video footage.

Conclusion: Inspection of the penetrating member, the film and the process suggest that material is not removed during the firing process.

5 1.4. Sterility of the blood barrier

In one embodiment, the adhesive blood barrier 1600 will be prepared and packaged in a cleanroom environment and then gamma sterilized. Their respective manufacturers have declared the selected film and foam suitable for gamma sterilization. All manufacturing will be completed by an EN 13485 certified manufacturer and in accordance with that standard.

10 The barrier film will be presented to the user on a sterilized impermeable carrier and covered by another impermeable protective. The blood barrier film is then only exposed to possible contaminants once it is removed from its packaging in preparation for use. Applicator tabs and location details will be help to reduce handling of the lancing area as much as possible.

15 1.5. Cross contamination between penetrating members

In the current solution very small amounts of blood may adhere to the penetrating member and travel back into the cartridge. Each penetrating member is contained within its own cavity that is separated from adjacent cavities and the mechanism. This separation is sufficient in size and geometry to prevent pathogens spreading. The adjacent unused sterile penetrating member is hermetically sealed up until the time of firing. Figure 42 Plan view of part of the penetrating member cartridge (protective foil not shown)” below show the layout of the cartridge in which the penetrating members are contained. From these drawings it can be seen that the distance between penetrating members is large enough to prevent pathogens traveling between penetrating members even were they not sealed.

25 1.6. Penetrating member Damage

Operation of the device may be impeded and pain levels increased if the penetrating member were to be damaged by the film before it entered the patient skin. To check damage did not occur 5 penetrating members were inspected before and after a lancing operation using the device prototype. The penetrating members showed no visible damage to the sharpened tip during the firing process.

30 1.7. Application of barrier

Incorrect application might place the high-density foam offset pad in the trajectory of the penetrating member or reduce the effectiveness of the foam in creating the air gap described above. To prevent such misapplication features are provided on the outer case of the fluid

sampling Pro to match the geometry of the barrier film. These features make misapplication obvious and reinforce the user instructions. The features are shown in

2. Appendix I: Instructions for application of barrier

Referring to the information below, one embodiment of the instructions for users of the 5 fluid sampling Pro Penetrating member Launcher Sterile Blood Barrier will be shown.

This device is for use by healthcare professionals only. It is recommended that the operator wear sterile gloves when using the device.

1. Prepare the skin of the patient in the area to be lanced with a sterile wipe.

2. Remove the protective covering from the packaging exposing a single item of 10 sterile barrier film by pulling on the tab provided. Remove the sterile barrier film from the carrier by pulling on the applicator tab provided. (See illustrations below)

3. Apply the adhesive side to the front area of the device ensuring that both the outer circular holes in the barrier film fit around the matching circular bosses on the front of the device.

15 4. Press the sterile barrier film to the front and underside of the case taking care not to touch the firing area of the barrier film.

5. Prepare a penetrating member by operating the slider on the side of the device and depressing the fire button once. (See Lancing Device User Instructions)

20 6. Press the center circular cutout in the foam front of the barrier film against the patients skin in the area to be lanced.

7. Lance the patient by depressing the fire button a second time.

8. Remove the device from the patients skin and take the blood sample from their skin.

25 9. Carefully remove the barrier film from the front of the device using the tab provided and dispose of it properly.

10. Check that outer case of device has not been contaminated by blood and if necessary clean it with disinfectant.

Figure 41 shows one embodiment of packaging for holding sterile barriers 1600. The packaging 1700 may include a sterile carrier 1702 and a protective cover 1704. Tabs 1706 may 30 be used to facilitate pealing of the protective covers 1704.

Figure 42 shows the possible areas of contamination and the barrier 1600 is designed to minimize the flow of blood to these areas or to prevent users from coming in to contact with any blood on these areas.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above 5 embodiments, the shield or other punch may be adapted for use with other cartridges disclosed herein or in related applications. With any of the above embodiments, a motor may be directly coupled to rotate the cartridge.

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that 10 the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited. U.S. Provisional Application No. 60/577,412 15 (Attorney Docket No. 38187-2737) and U.S. Provisional Application No. 60/577,376 (Attorney Docket No. 38187-2737) are fully incorporated herein by reference for all purposes.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as 20 is reasonable.

WHAT IS CLAIMED IS:

- 1 1. A fluid sampling device comprising:
2 a housing;
3 a slider located on a surface of said housing, said slider movable in a linear
4 direction to rotate said cartridge to bring an unused penetrating member into position for
5 use.

- 1 2. A fluid sampling device comprising:
2 a housing;
3 a cartridge defining a plurality of cavities, said cartridge sized to fit within
4 said housing; and
5 a plurality of penetrating members at least partially contained in said
6 cavities of the cartridge wherein the penetrating members are slidably movable to extend
7 outward from said cartridge to penetrate tissue, said cavities each having a longitudinal
8 opening providing access to an elongate portion of the penetrating member;
9 a sterility barrier coupled to said cartridge, said sterility barrier covering a
10 plurality of the longitudinal openings, wherein the sterility barrier covering the lateral
11 openings is configured to be moved so that the elongate portion may be accessed by the
12 gripper without touching the barrier; and
13 a slider located on a surface of said housing, said slider movable in a linear
14 direction to rotate said cartridge to bring an unused penetrating member into position for
15 use;
16 a tooth gear coupled to said slider to control a distance said slider can
17 travel;
18 a follower coupled to said slider;
19 a cam surface engaged by said follower to lift said cartridge a desired
20 distance above a first position to allow for rotation of the cartridge without engaging a
21 gripper used to advance the penetrating member.

- 1 3. The device of claim 1 wherein said cam surface is aligned parallel
2 to said slider.

1 4. The device of claim 1 wherein said linear motion of the cam rotates
2 the cartridge and moves a plunger to break the sterility barrier on the cartridge.

1 5. The device of claim 1 wherein cam surface comprise a linear strip
2 of material with at least two raised portions and two depressed portions.

1 6. A device for use in penetrating tissue to obtain a body fluid sample,
2 comprising:

3 a cartridge; and
4 a plurality of penetrating members slidably coupled to the cartridge, each
5 of said penetrating members having a distal end sufficiently sharp to pierce tissue and
6 each of said penetrating members being moveable relative to the other ones of the
7 penetrating members, so that the distal end of the respective penetrating member is
8 movable to penetrate tissue;

9 wherein each of said penetrating member is a bare lancet does not
10 penetrate an outer sterility barrier during actuation.

1 7. A device comprising:

2 a cartridge having a plurality of cavities; and
3 a plurality of penetrating members at least partially contained in said
4 cavities of the single cartridge wherein the penetrating members are slidably movable to
5 extend outward from lateral openings on said cartridge to penetrate tissue;

6 a sterility barrier coupled to said cartridge, said sterility barrier covering a
7 plurality of said lateral openings, wherein the sterility barrier covering the lateral
8 openings is configured to be moved so that a penetrating member exits the lateral opening
9 without contacting the barrier.

1 8. The device of claim 7 wherein the sterility barrier covering the
2 lateral openings is configured to be moved substantially vertically so that a penetrating
3 member exits the lateral opening without contacting the barrier.

1 9. A device comprising:

2 a housing;
3 a penetrating member driver;
4 a cartridge containing a plurality of penetrating members;

5 a display on said cartridge;
6 a linear slider on the housing, said slider coupled to a rod;
7 said rod moving with said slider, said rod having at least one roller
8 using the linear motion of the slider to rotate the cartridge, punch open a
9 new cavity and load a new penetrating member.

1 10. A method of indexing comprising:
2 moving a linear slider;
3 said linear slider coupled to a rod;
4 said rod moving with said slider, said rod having at least one roller
5 using the linear motion of the slider and linear motion of the rod to push at
6 least one linear slider and to roll a roller along a linear cam surfaces to lift clear a drive
7 assembly, rotate the cartridge, punch open a new cavity and load a new penetrating
8 member.

1 11. A fluid sampling device comprising: [2738]
2 a housing;
3 a cartridge defining a plurality of cavities, said cartridge sized to fit within
4 said housing; and

5 a plurality of penetrating members at least partially contained in said
6 cavities of the cartridge wherein the penetrating members are slidably movable to extend
7 outward from said cartridge to penetrate tissue, said cavities each having a longitudinal
8 opening providing access to an elongate portion of the penetrating member;

9 a sterility barrier coupled to said cartridge, said sterility barrier covering a
10 plurality of the longitudinal openings, wherein the sterility barrier covering the lateral
11 openings is configured to be moved so that the elongate portion may be accessed by the
12 gripper without touching the barrier; and

13 a replaceable tissue interface barrier located on said housing, wherein said
14 interface is replaced after each lancing event to prevent fluid contamination between
15 different users.

1 12. The device of claim 11 wherein said replaceable tissue interface is
2 positioned about an opening on said housing where said penetrating members extend
3 outward to engage tissue on a user to obtain a fluid sample.

1 13. The device of claim 11 wherein each of said cavities further
2 include a lateral opening.

1 14. The device of claim 11 wherein said replaceable tissue interface
2 comprising a plurality of individually removable sheets of material, wherein one sheet is
3 removed prior to each lancing event to uncover a sterile unused sheet to provide an
4 uncontaminated surface for the next user to use.

1 15. A device for use in penetrating tissue to obtain a body fluid sample,
2 comprising:

3 a cartridge; and
4 a plurality of penetrating members slidably coupled to the cartridge, each
5 of said penetrating members having a distal end sufficiently sharp to pierce tissue and
6 each of said penetrating members being moveable relative to the other ones of the
7 penetrating members, so that the distal end of the respective penetrating member is
8 movable to penetrate tissue;

9 wherein each of said penetrating member is a bare lancet does not
10 penetrate an outer, removable sterility barrier during actuation.

1 16. A device comprising:

2 a cartridge having a plurality of cavities; and
3 a plurality of penetrating members at least partially contained in said
4 cavities of the single cartridge wherein the penetrating members are slidably movable to
5 extend outward from lateral openings on said cartridge to penetrate tissue;

6 a sterility barrier coupled to said cartridge, said sterility barrier covering a
7 plurality of said lateral openings, wherein the sterility barrier covering the lateral
8 openings is configured to be moved so that a penetrating member exits the lateral opening
9 without contacting the barrier.

1 17. The device of claim 16 further comprising a fluid contamination
2 barrier located on a housing using said device, said barrier being removed and replaced
3 by a clean barrier prior to each lancing event.

1 18. A method for obtaining a fluid sample comprising:

2 removing the protective covering from the packaging exposing a single
3 item of sterile barrier film by pulling on the tab provided;
4 pressing the sterile barrier film to the front and underside of the case;
5 preparing a penetrating member by operating the slider on the side of the
6 device and depressing the fire button once;
7 pressing the center circular cutout in the foam front of the barrier film
8 against the patients skin in the area to be lanced;
9 lancing the patient;
10 removing the barrier film from the front of the device; and
11 checking that outer case of device has not been contaminated by blood and
12 if necessary clean it with disinfectant.

1 19. A method for obtaining a fluid sample comprising:
2 preparing the skin of the patient in the area to be lanced with a sterile
3 wipe;
4 removing the protective covering from the packaging exposing a single
5 item of sterile barrier film by pulling on the tab provided;
6 removing the sterile barrier film from the carrier by pulling on the
7 applicator tab provided;
8 applying the adhesive side to the front area of the device ensuring that both
9 the outer circular holes in the barrier film fit around the matching circular bosses on the
10 front of the device;
11 pressing the sterile barrier film to the front and underside of the case
12 taking care not to touch the firing area of the barrier film;
13 preparing a penetrating member by operating the slider on the side of the
14 device and depressing the fire button once;
15 pressing the center circular cutout in the foam front of the barrier film
16 against the patients skin in the area to be lanced;
17 lancing the patient by depressing the fire button a second time;
18 removing the device from the patients skin and take the blood sample from
19 their skin;
20 removing the barrier film from the front of the device using the tab
21 provided and dispose of it properly; and

22 checking that outer case of device has not been contaminated by blood and
23 if necessary clean it with disinfectant.

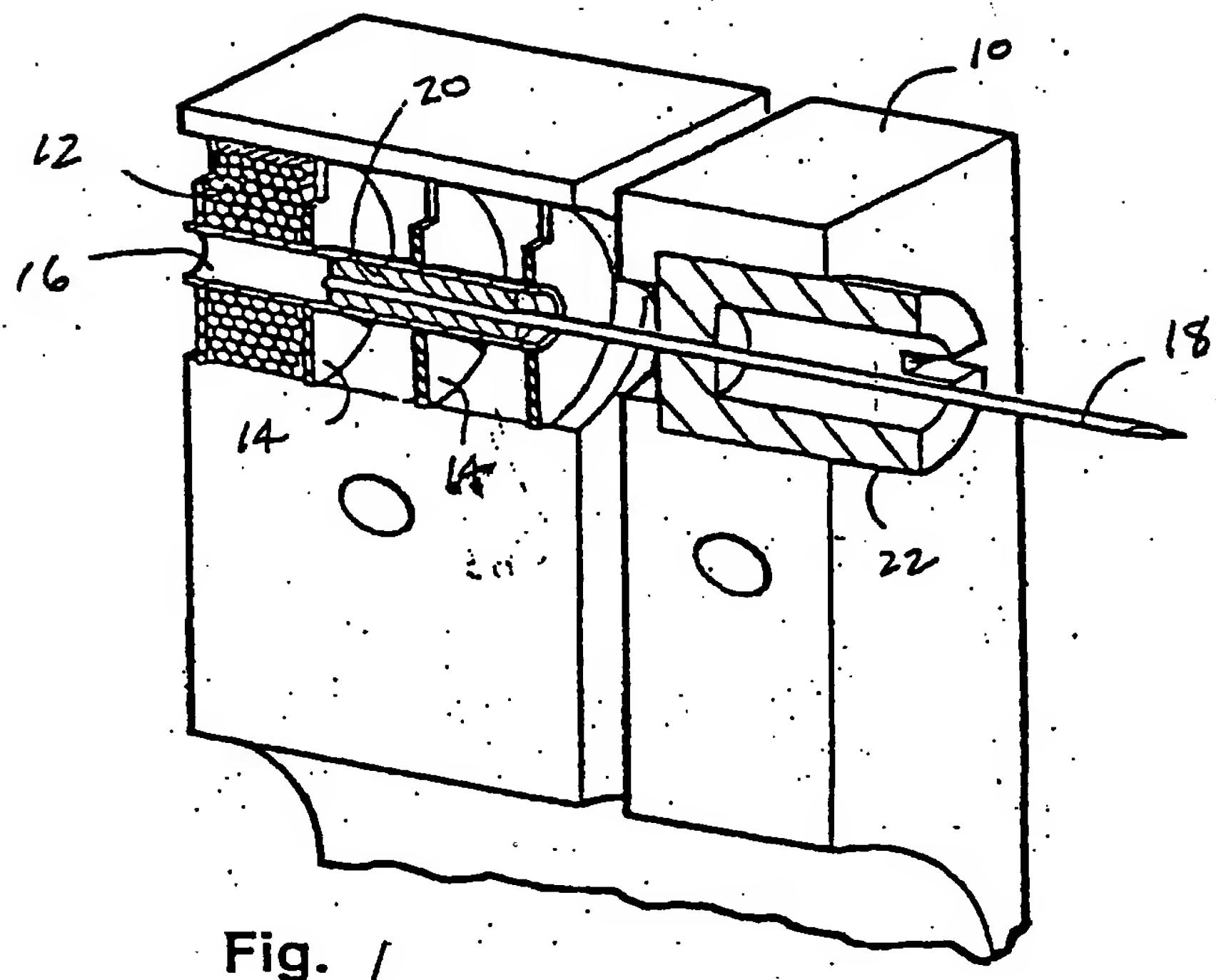


Fig. 1

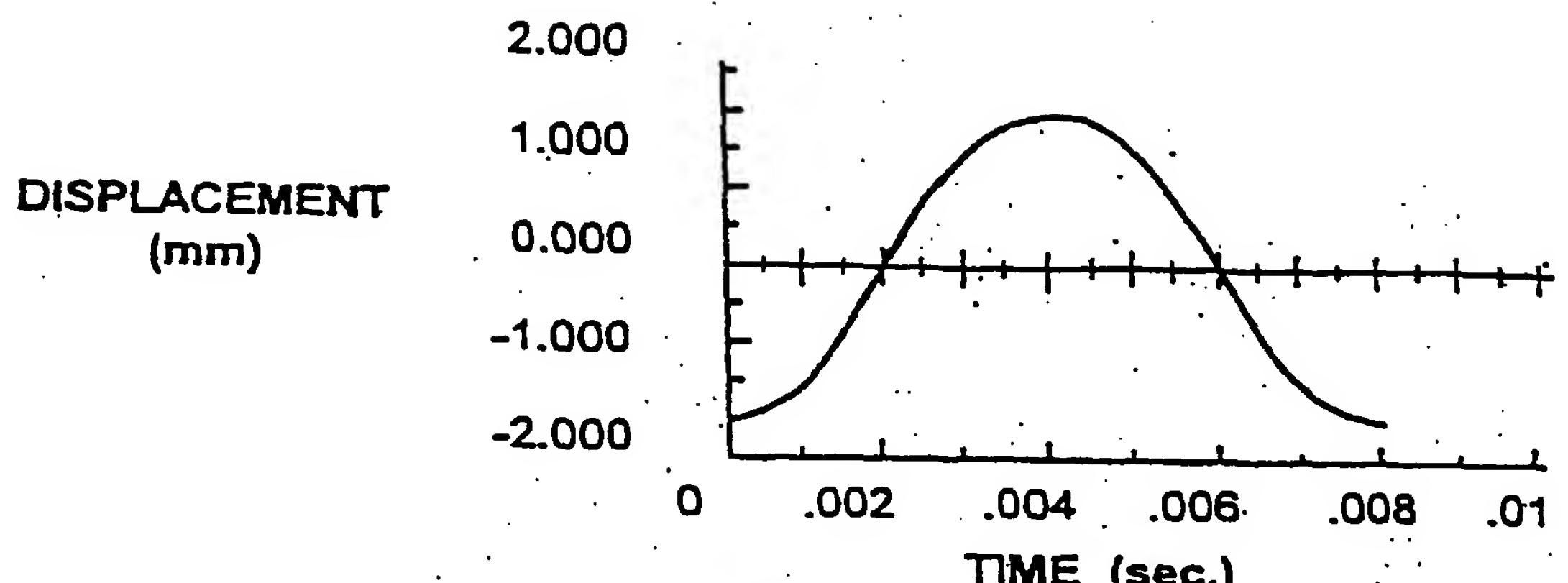


Fig. 2A

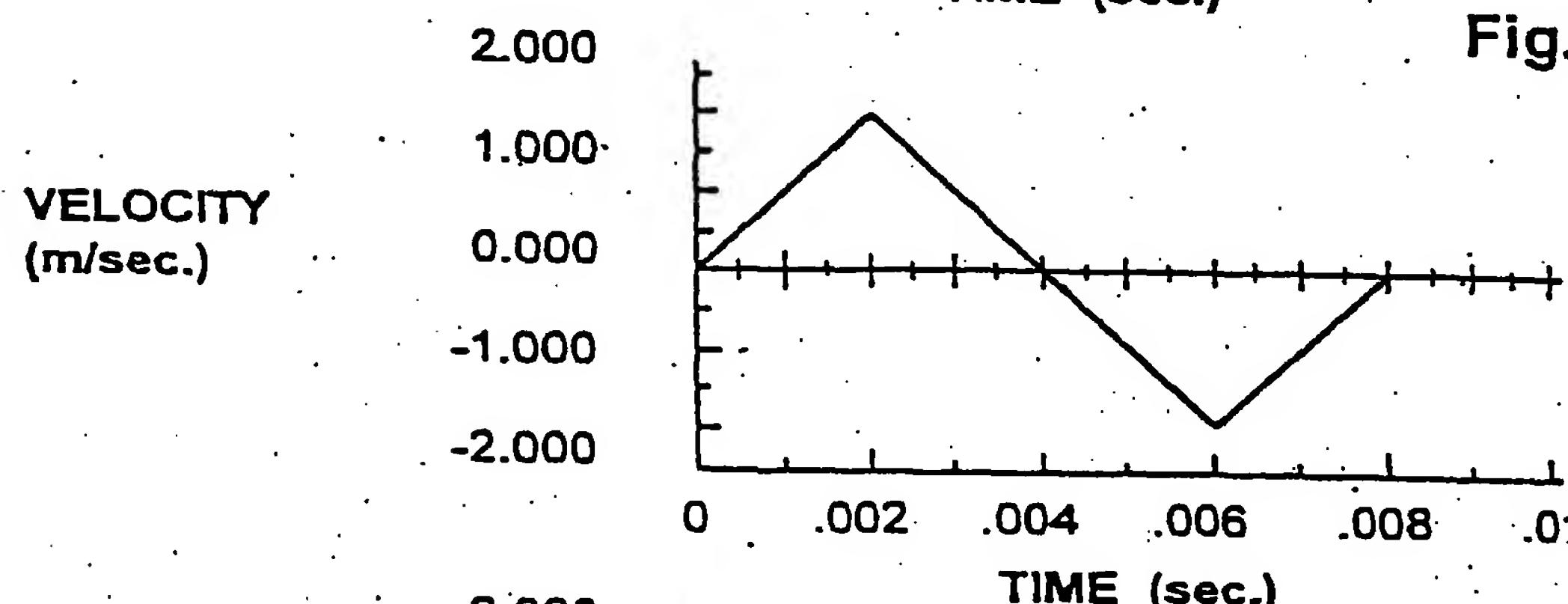


Fig. 2B

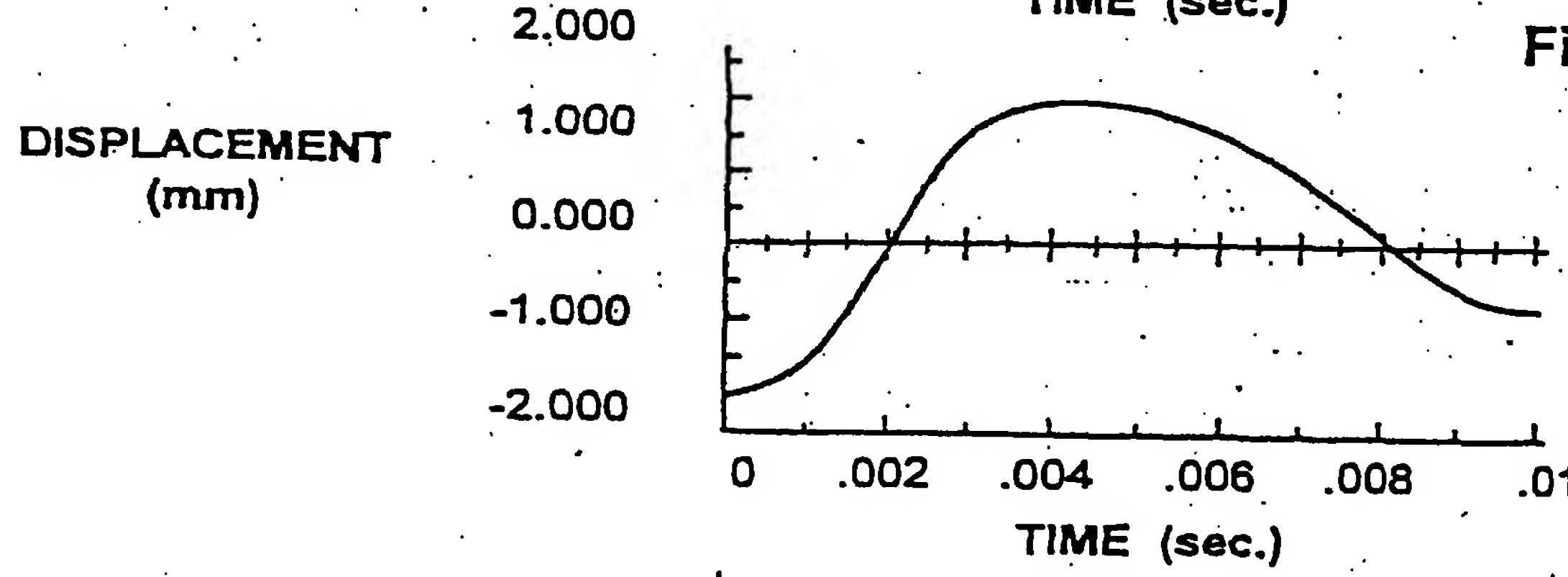


Fig. 2C

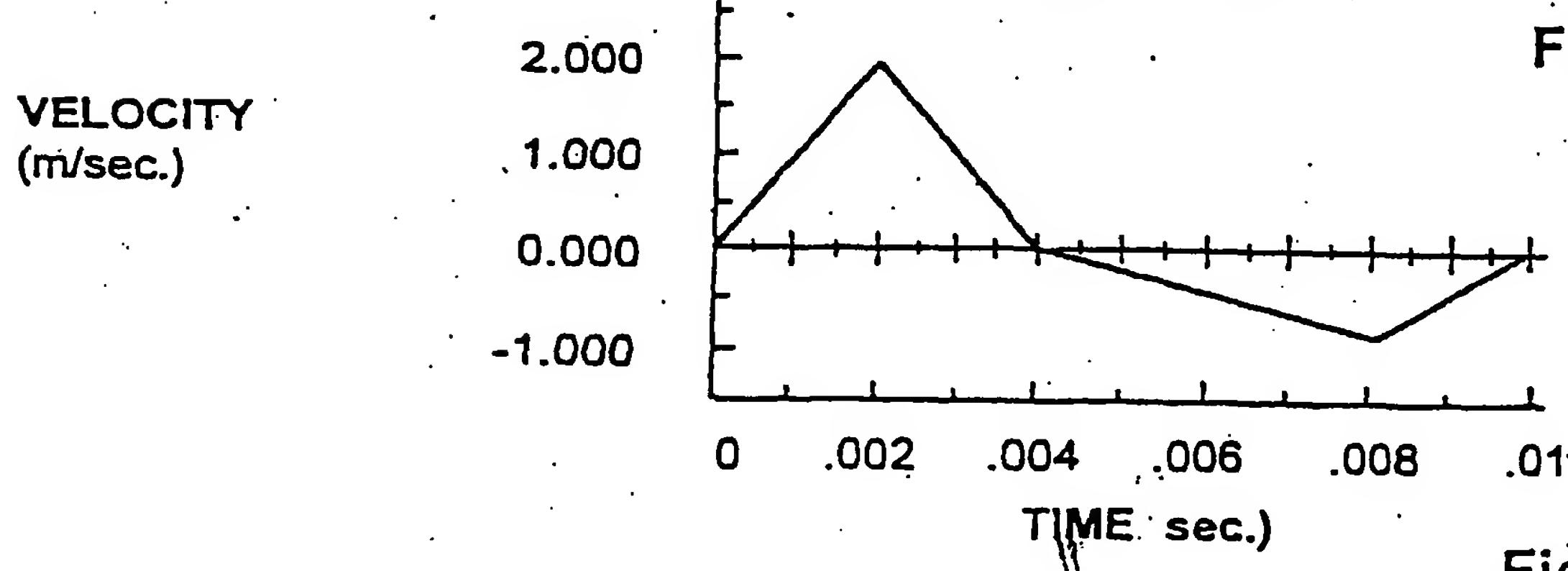


Fig. 2D

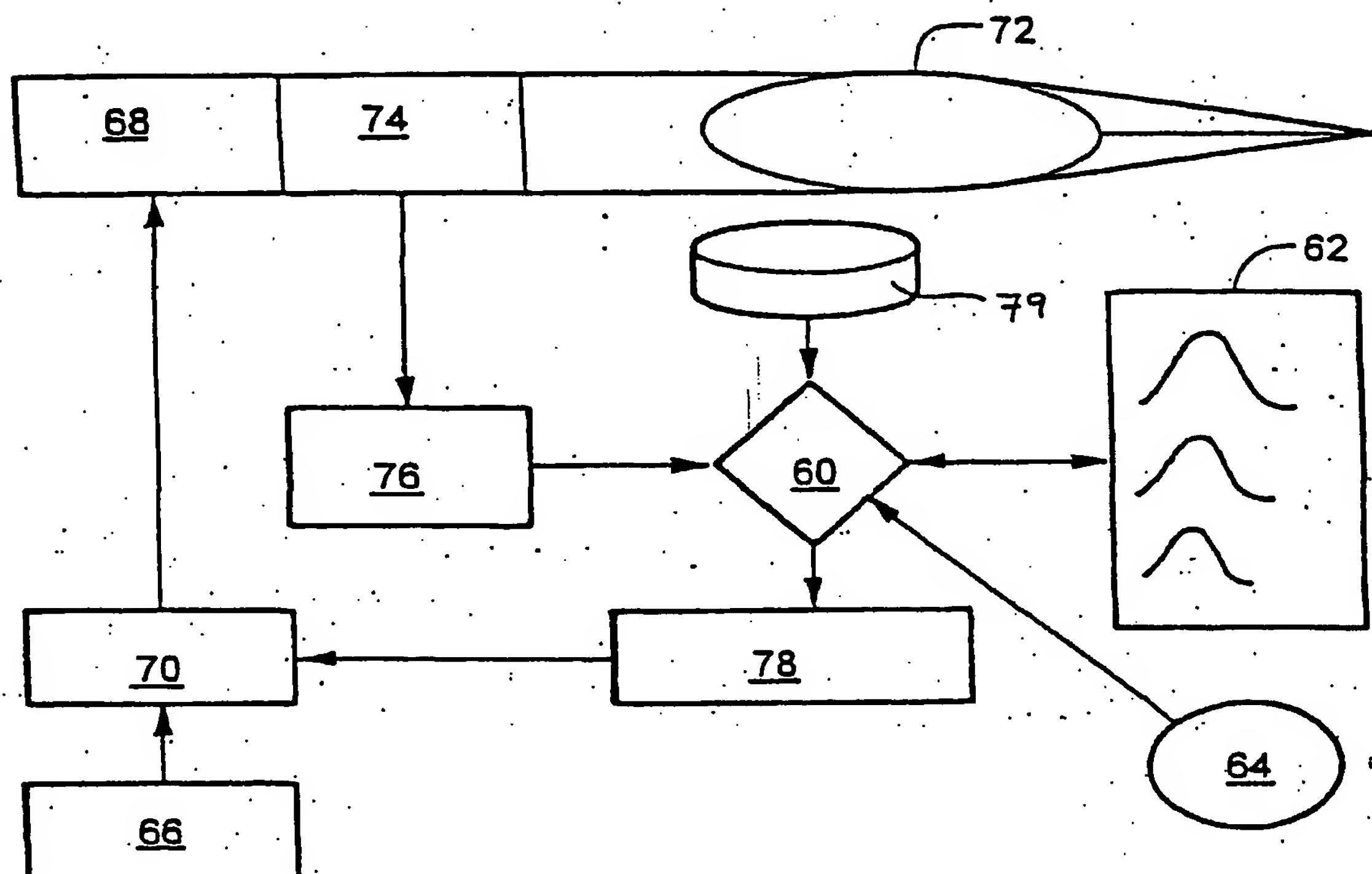


Fig. 3

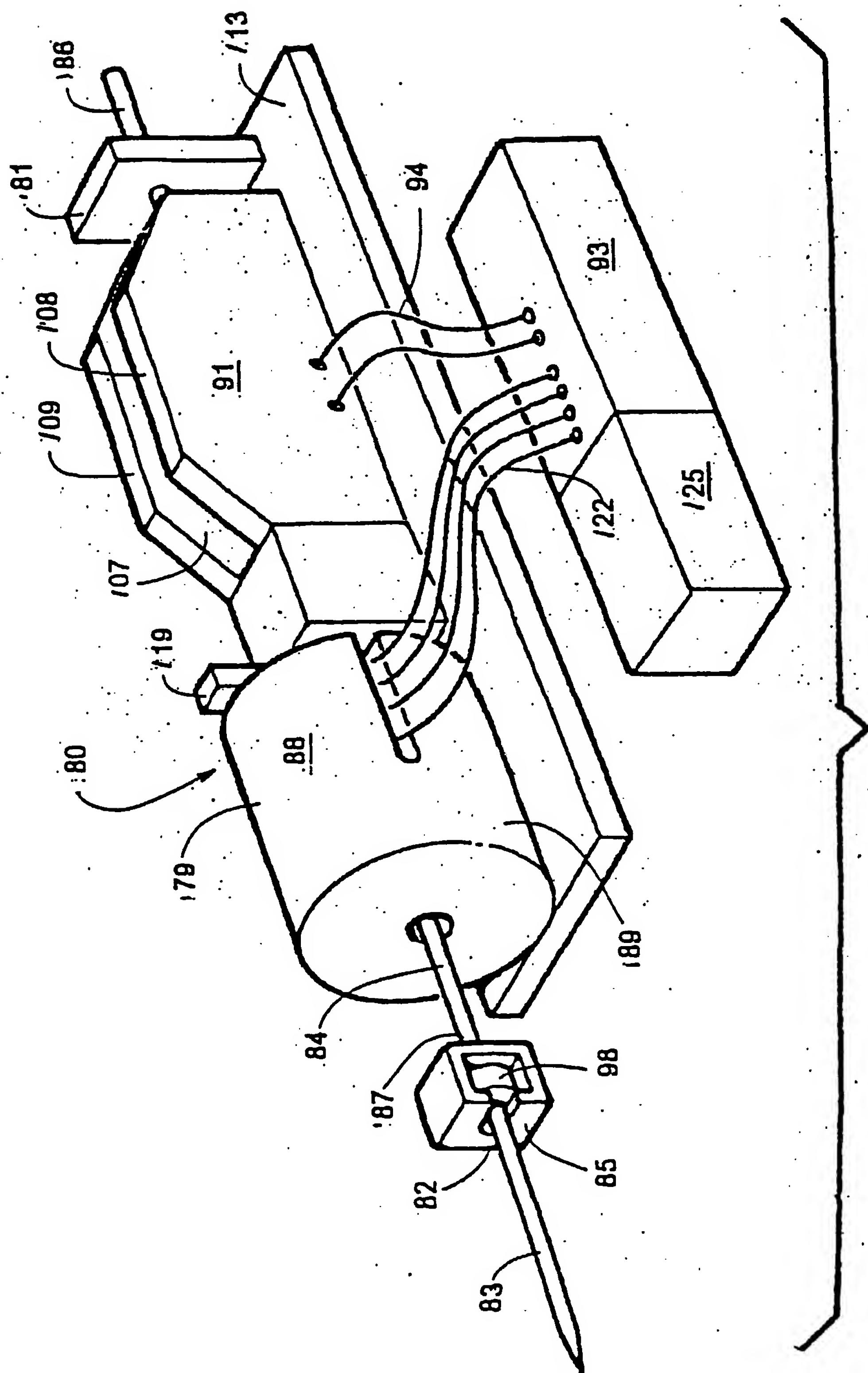
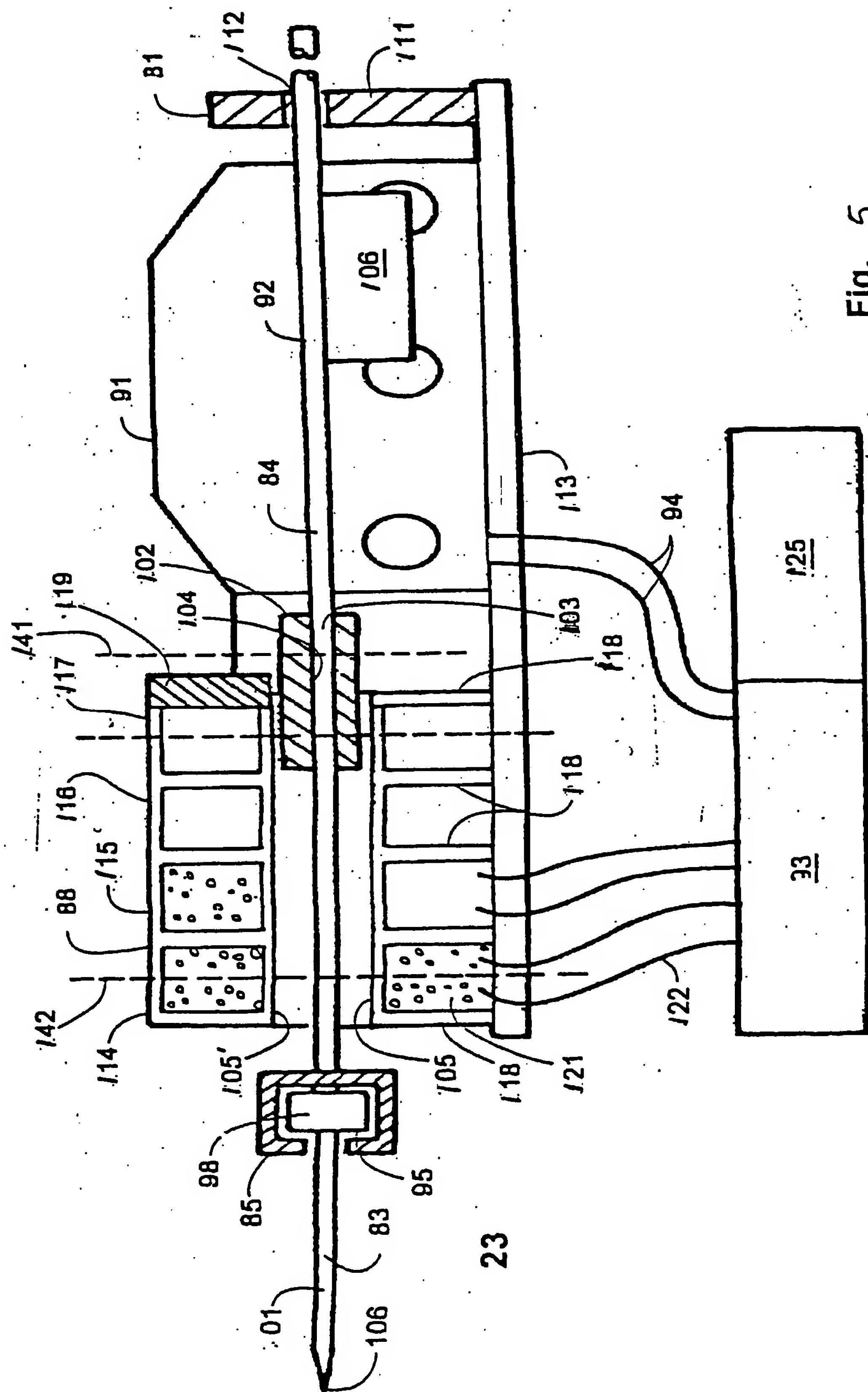


Fig. 4



5
Fig.

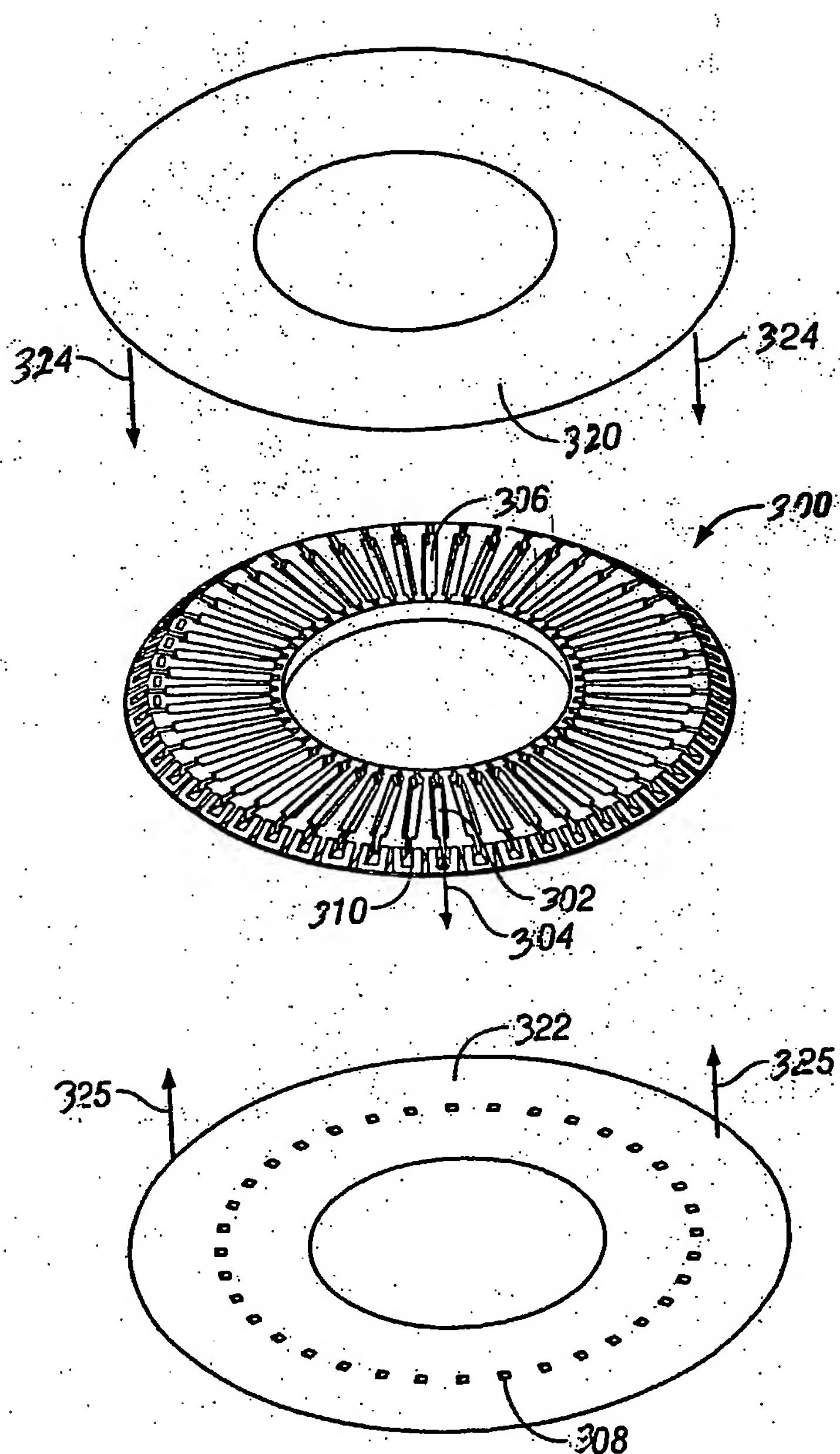


FIG. 6

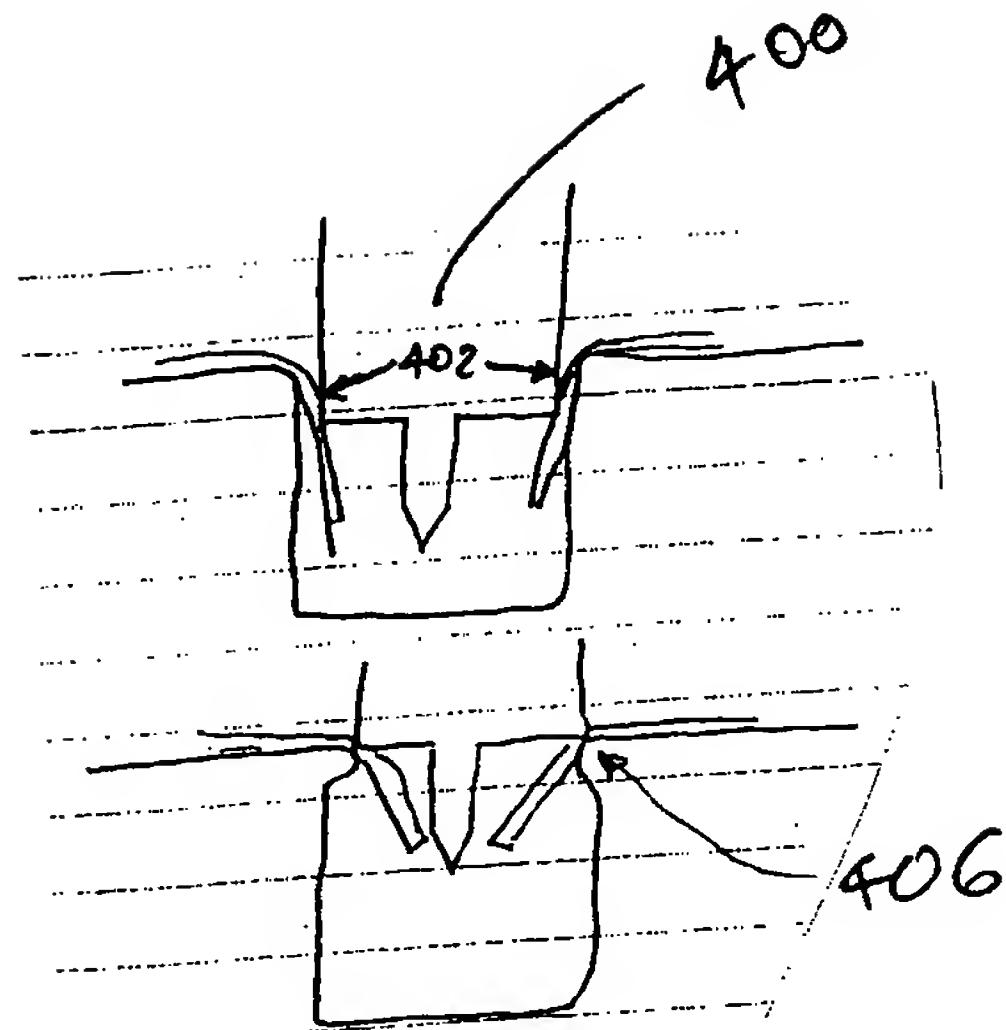


FIG - 7

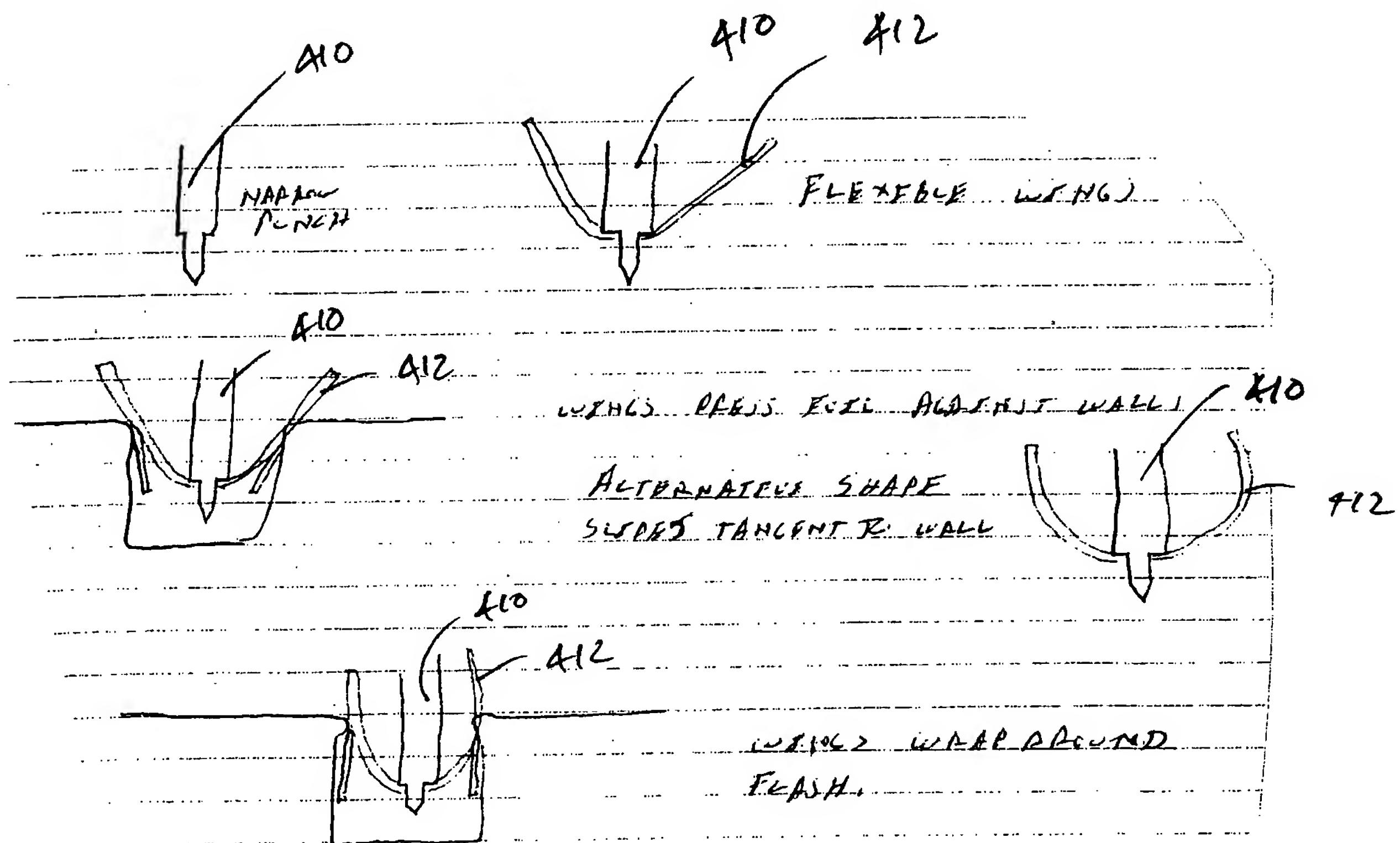


FIG - 8

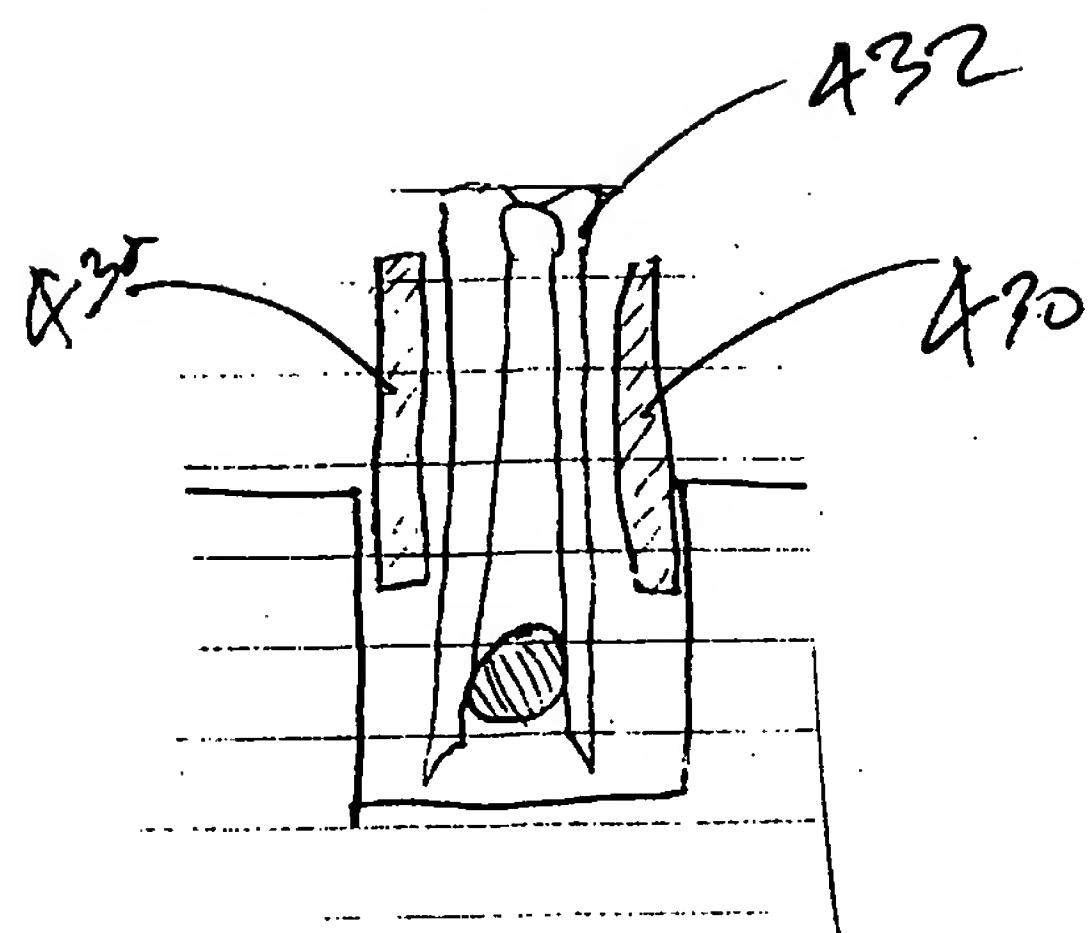


FIG-9

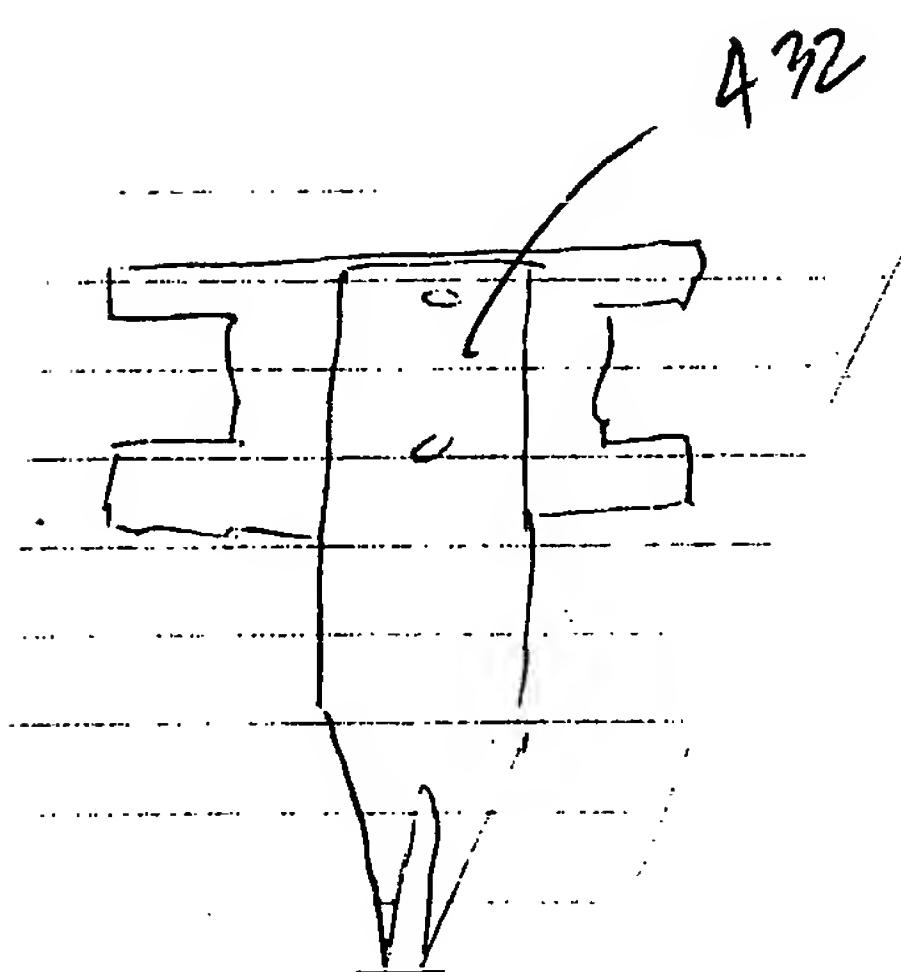


FIG-10

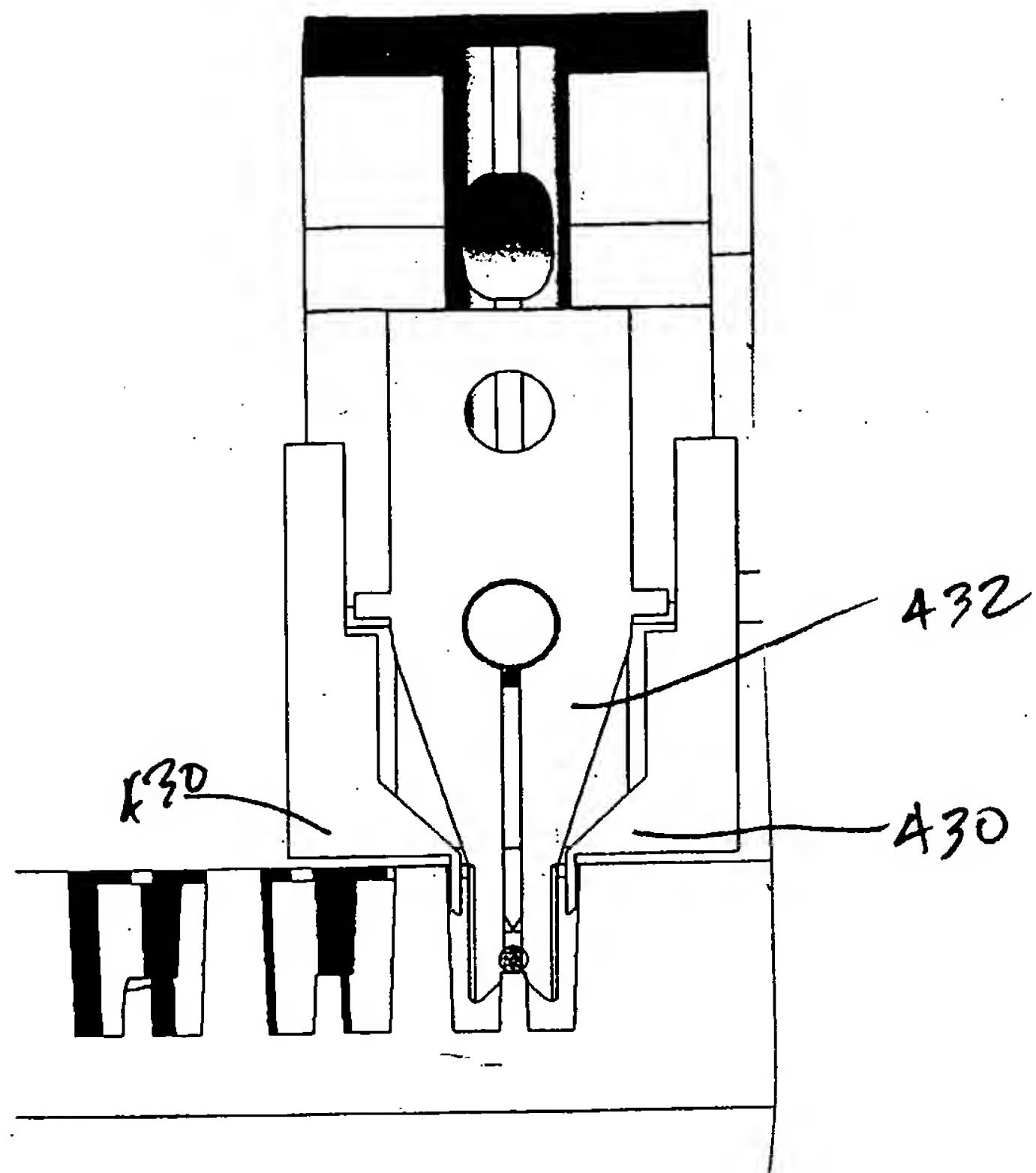


FIG-11

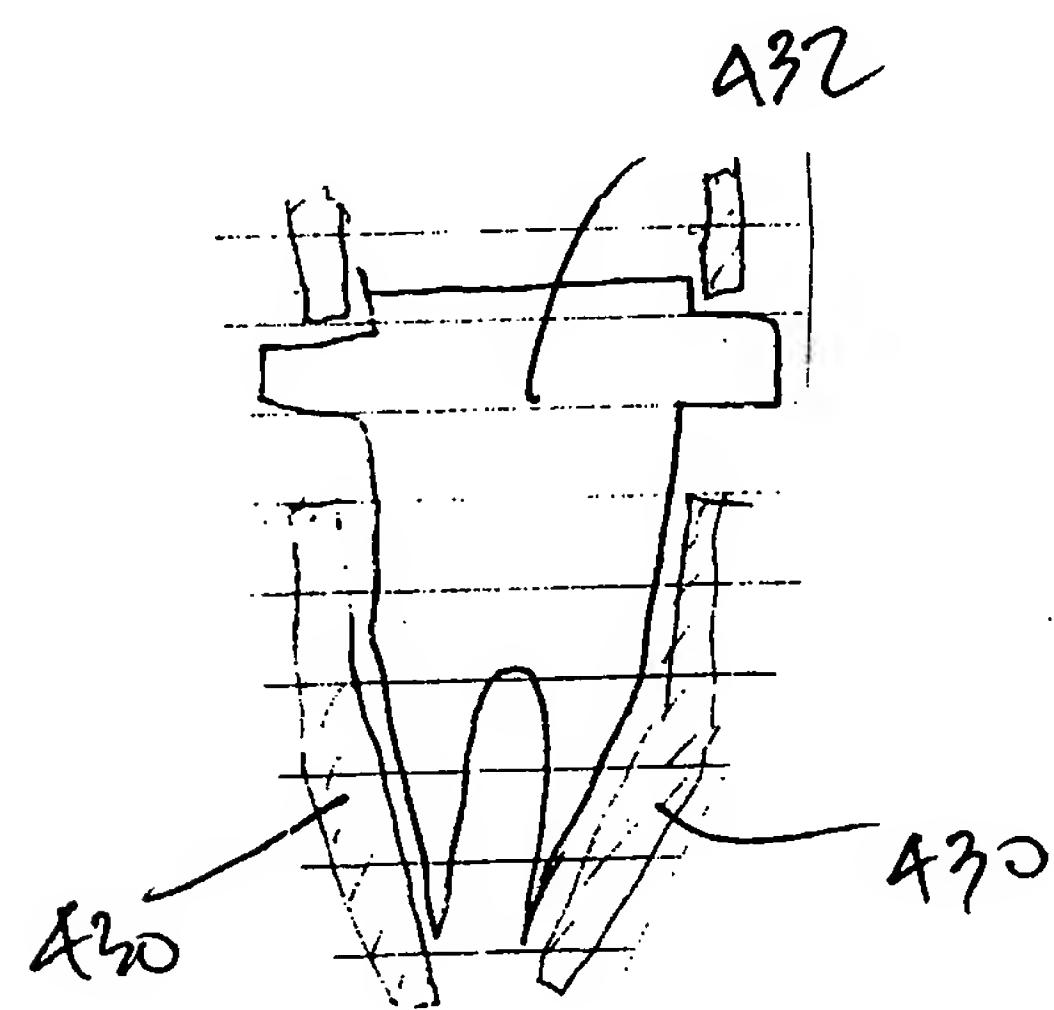


FIG-12

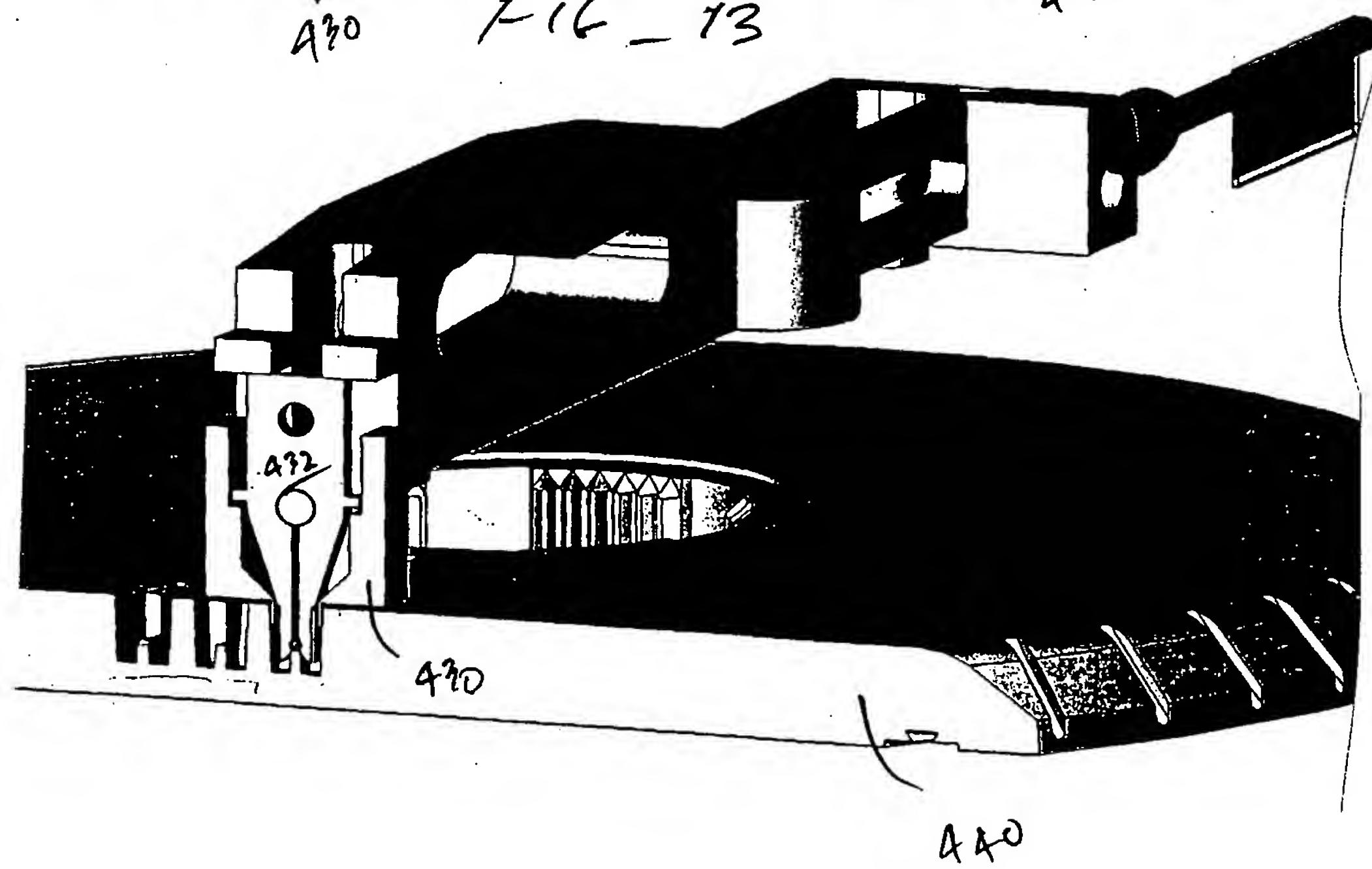
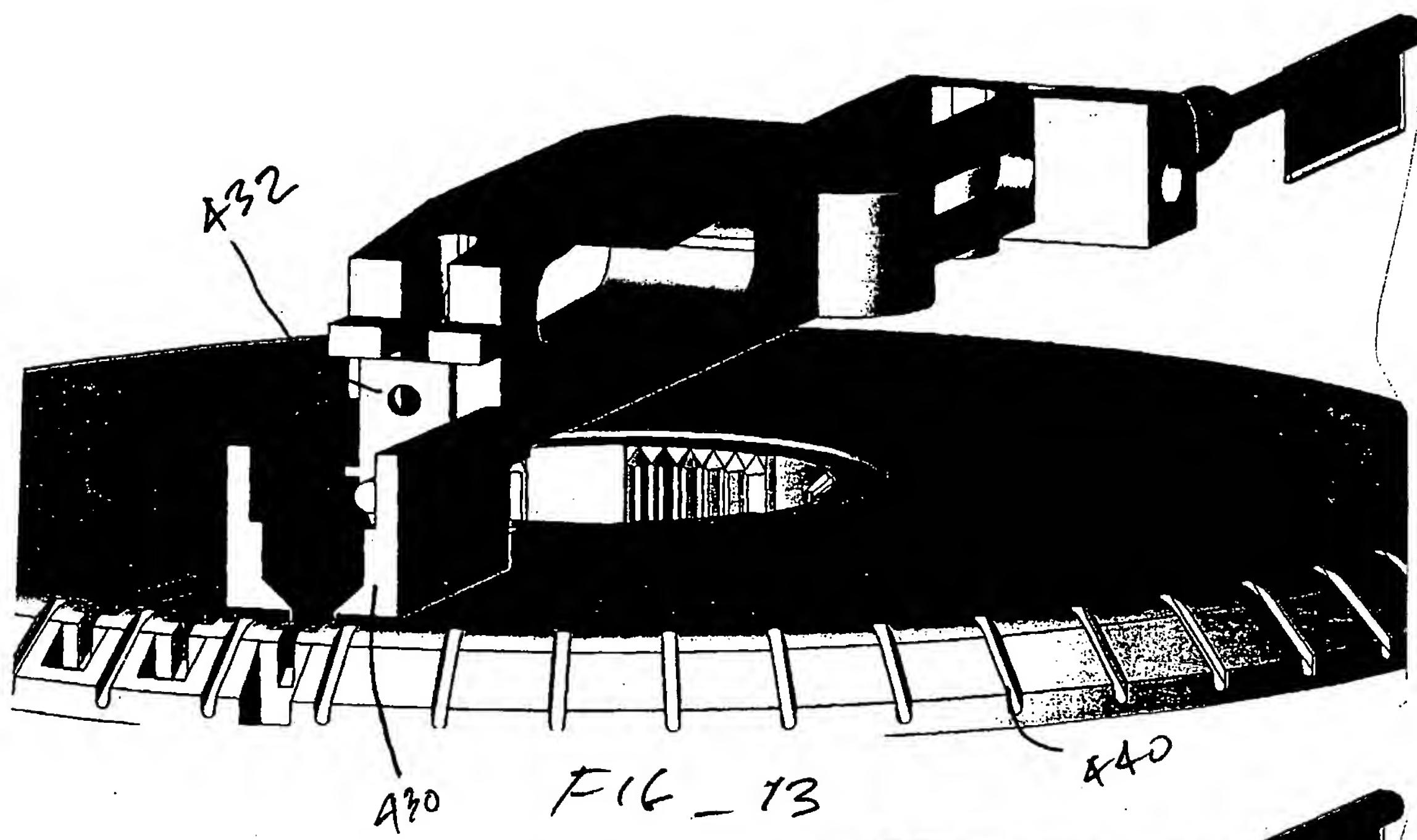
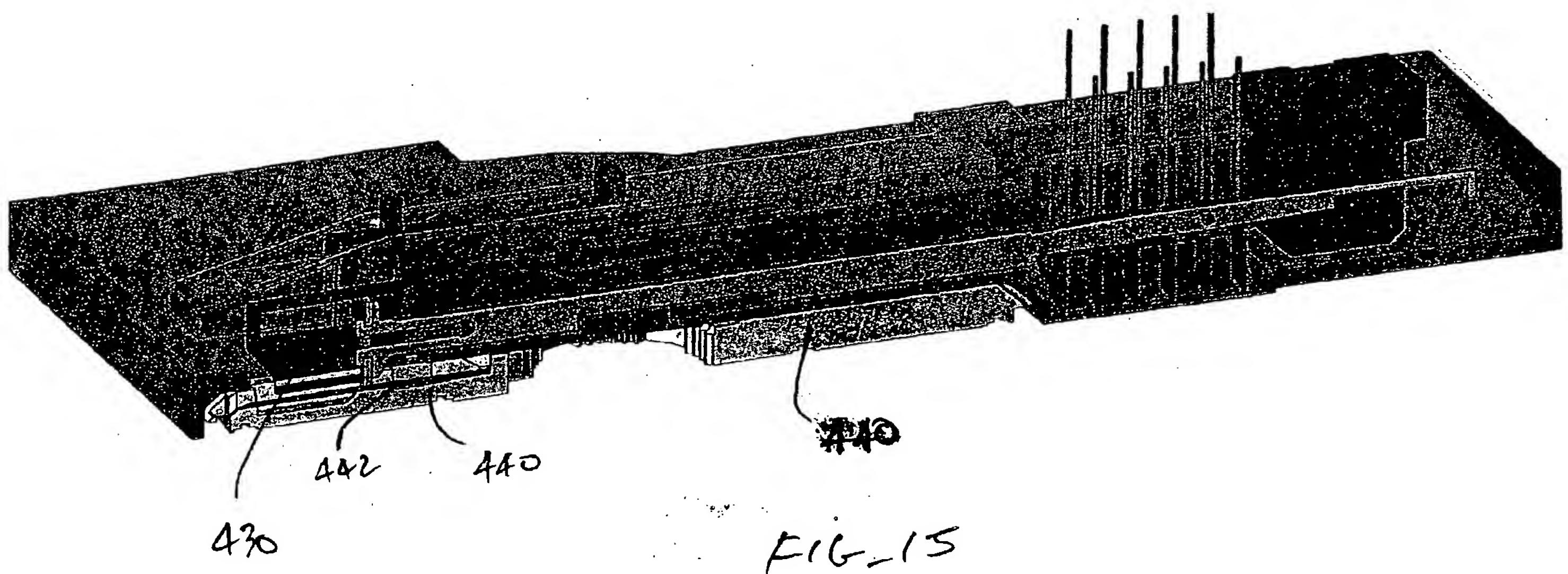
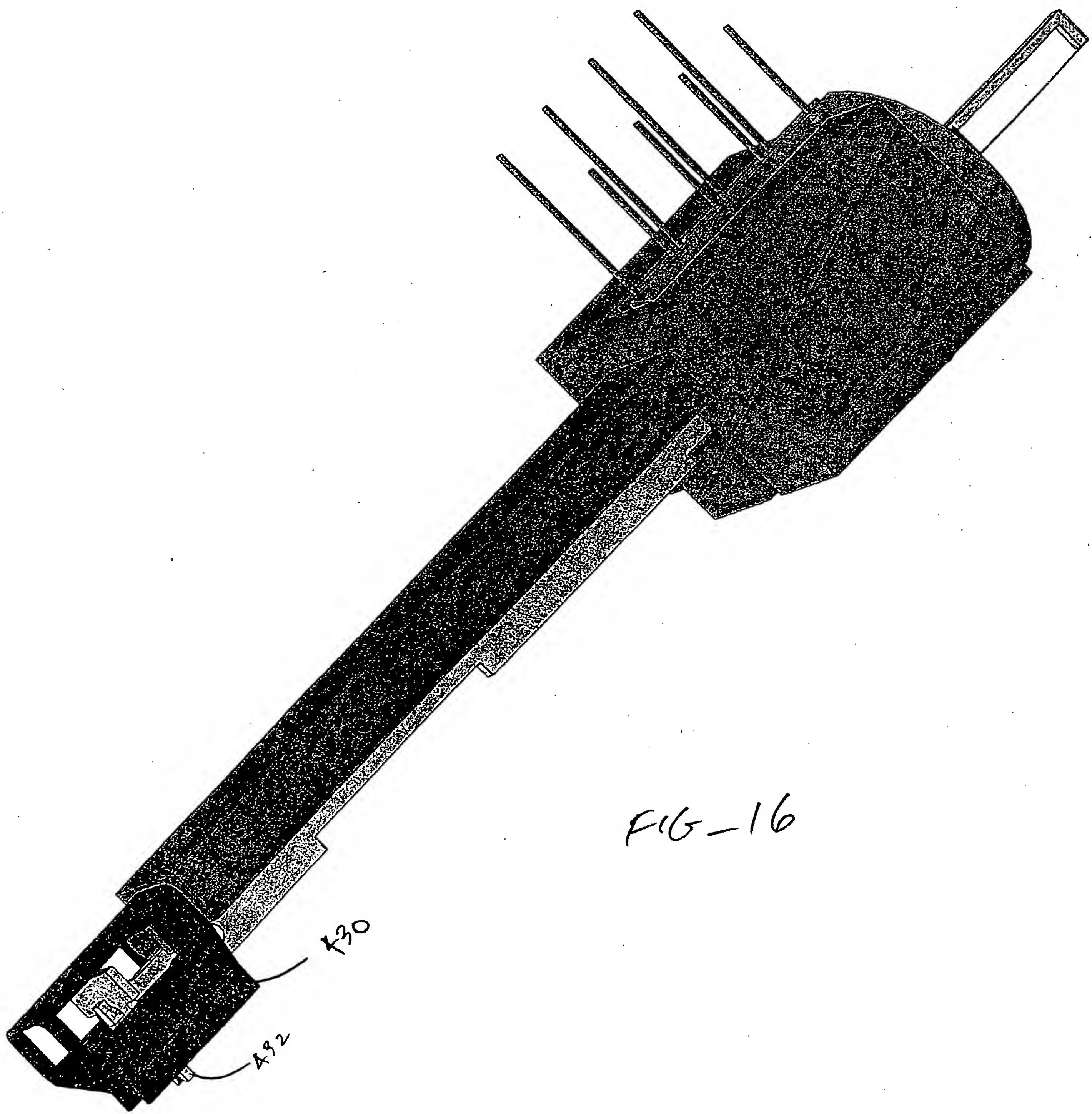


FIG - 14





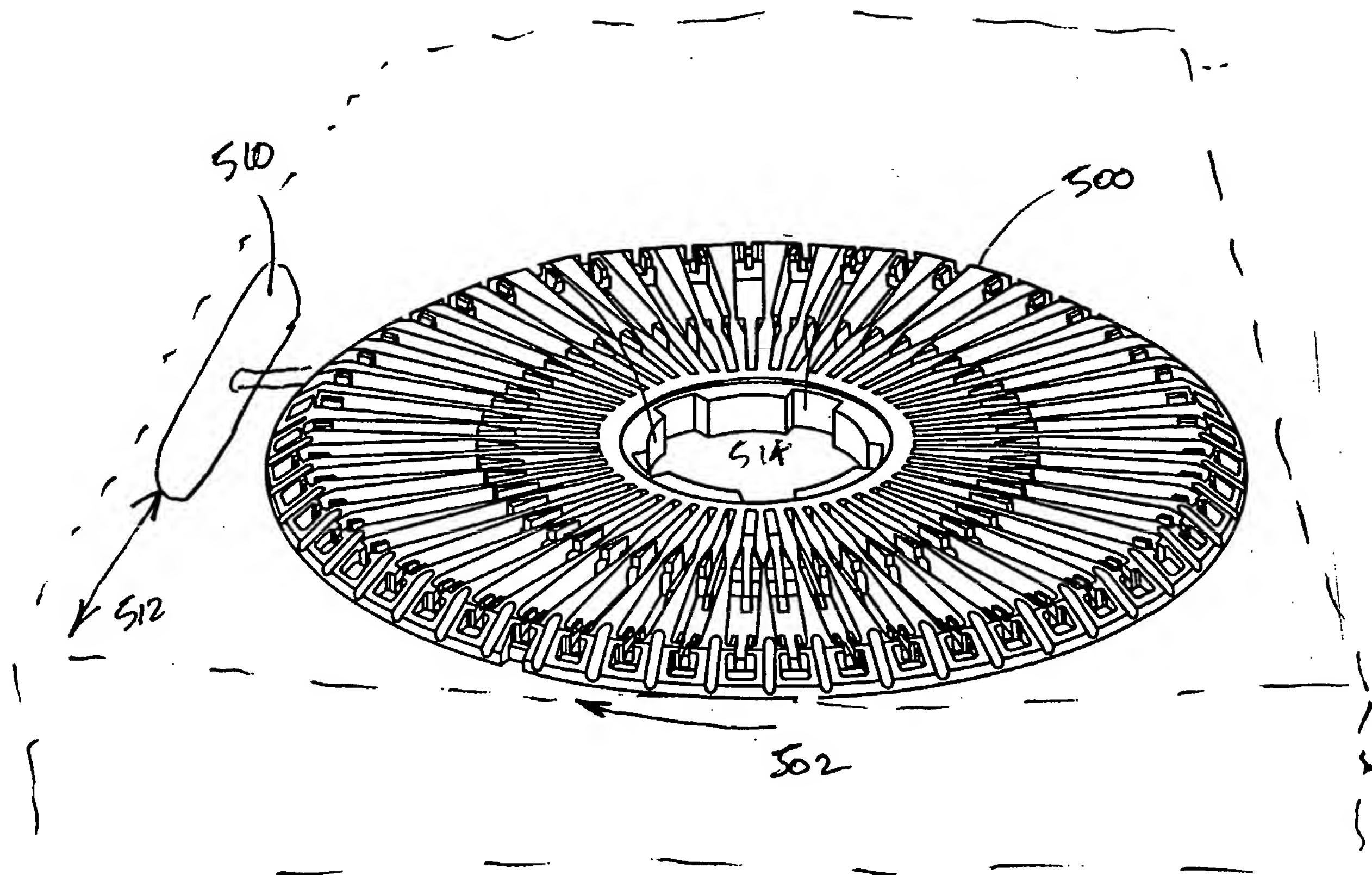


FIG-17

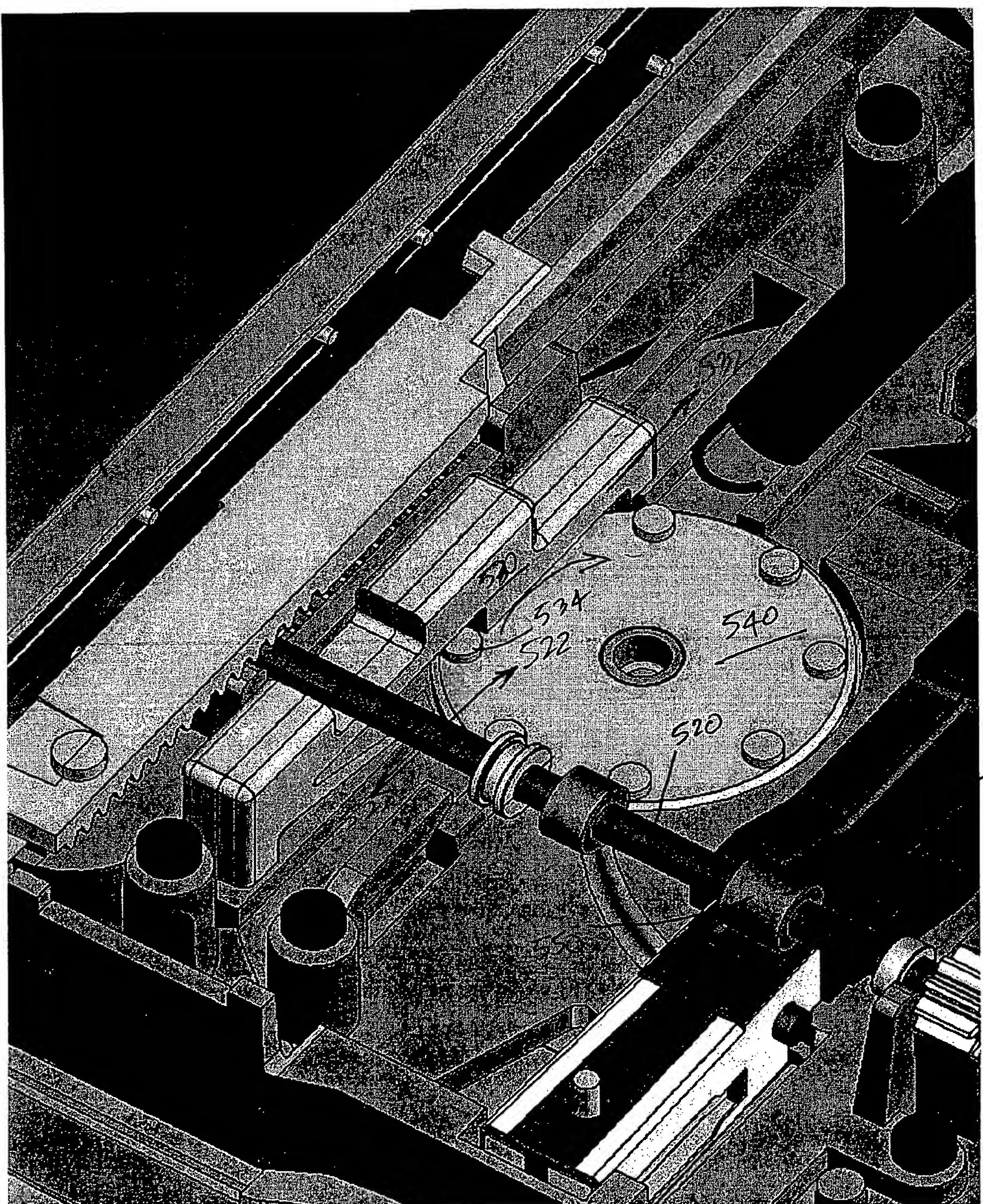


FIG- 18

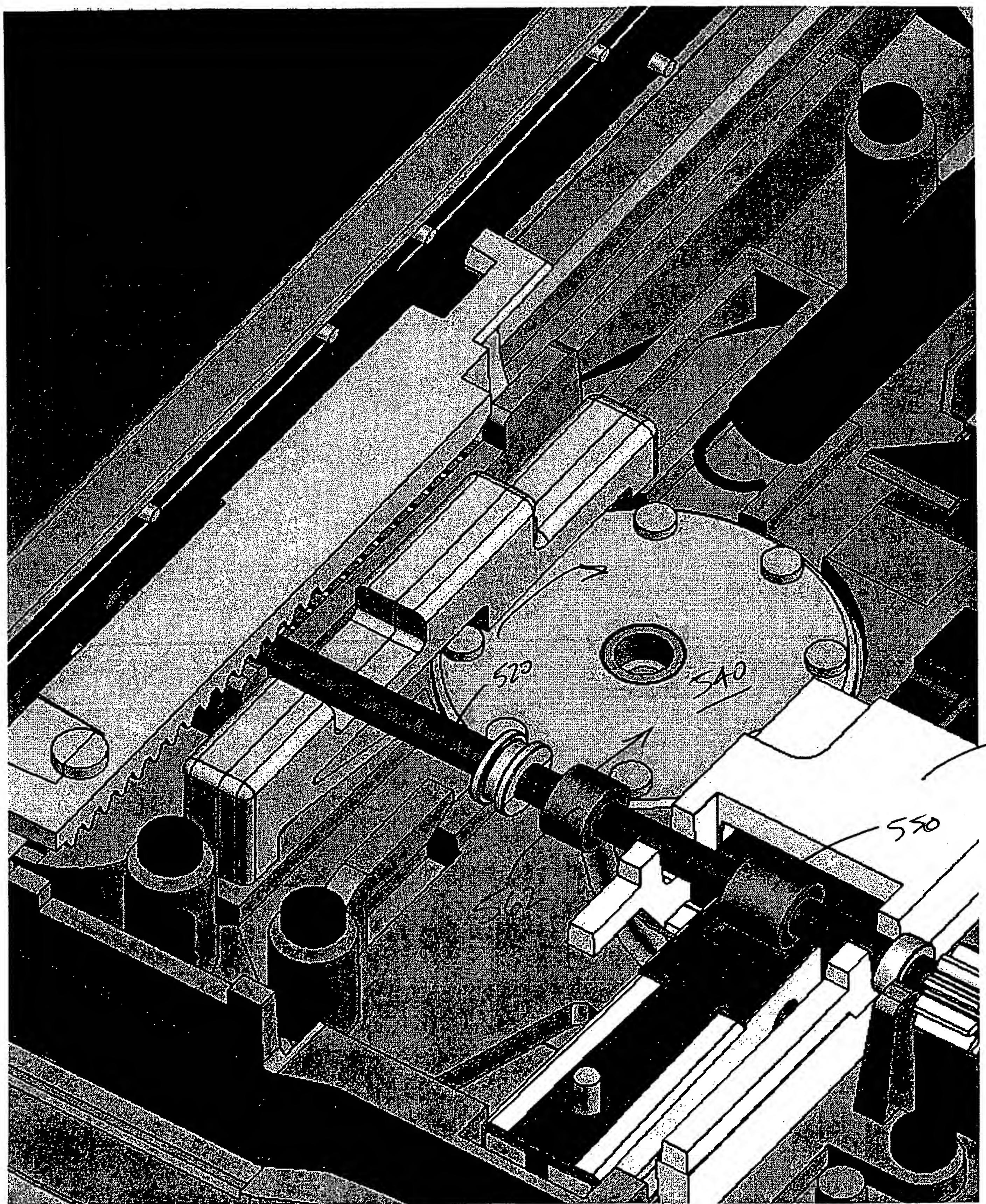


FIG-19

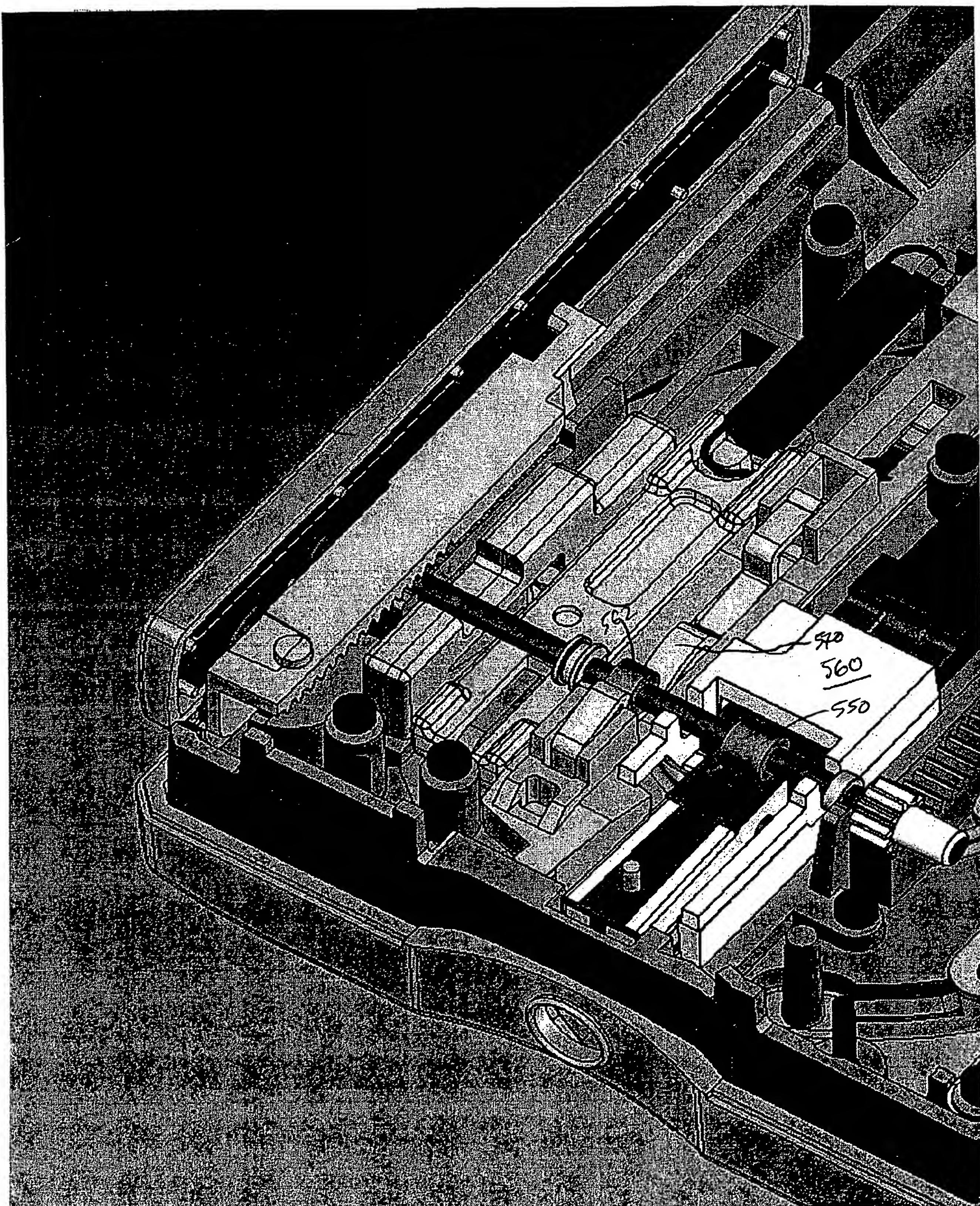
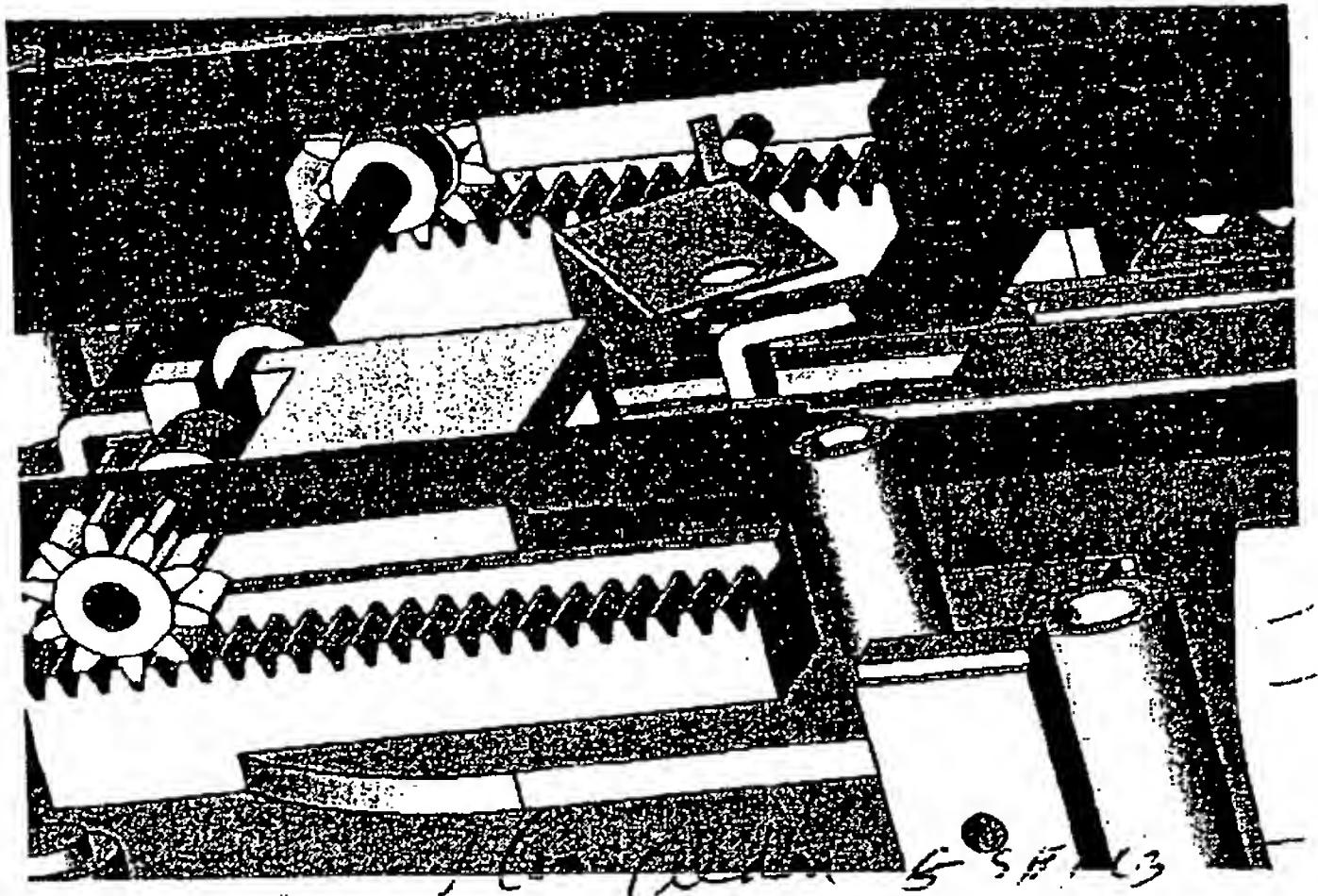


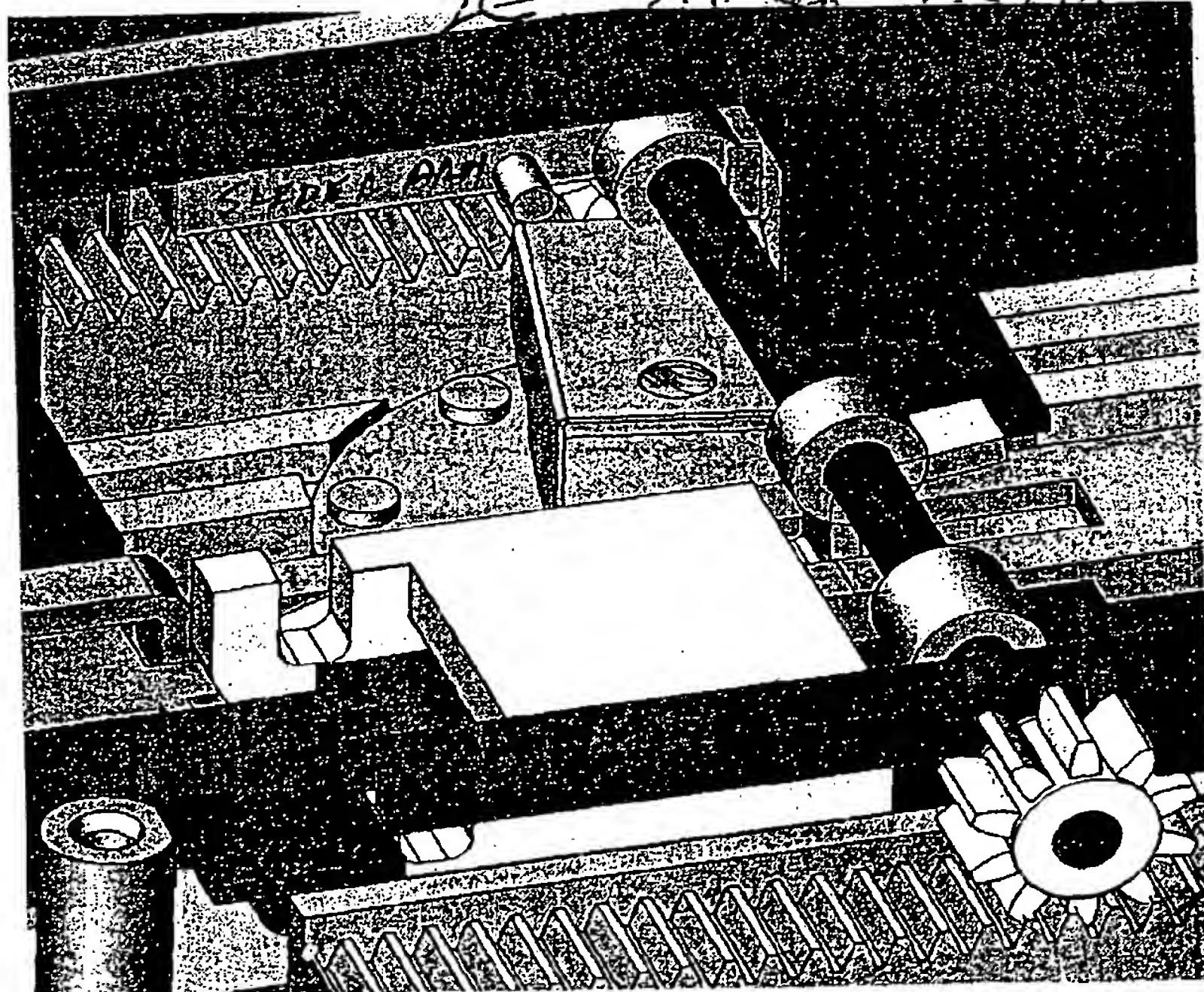
FIG - 20

856C3



VS61

16 Center - 650m



Alan Alder 856C3

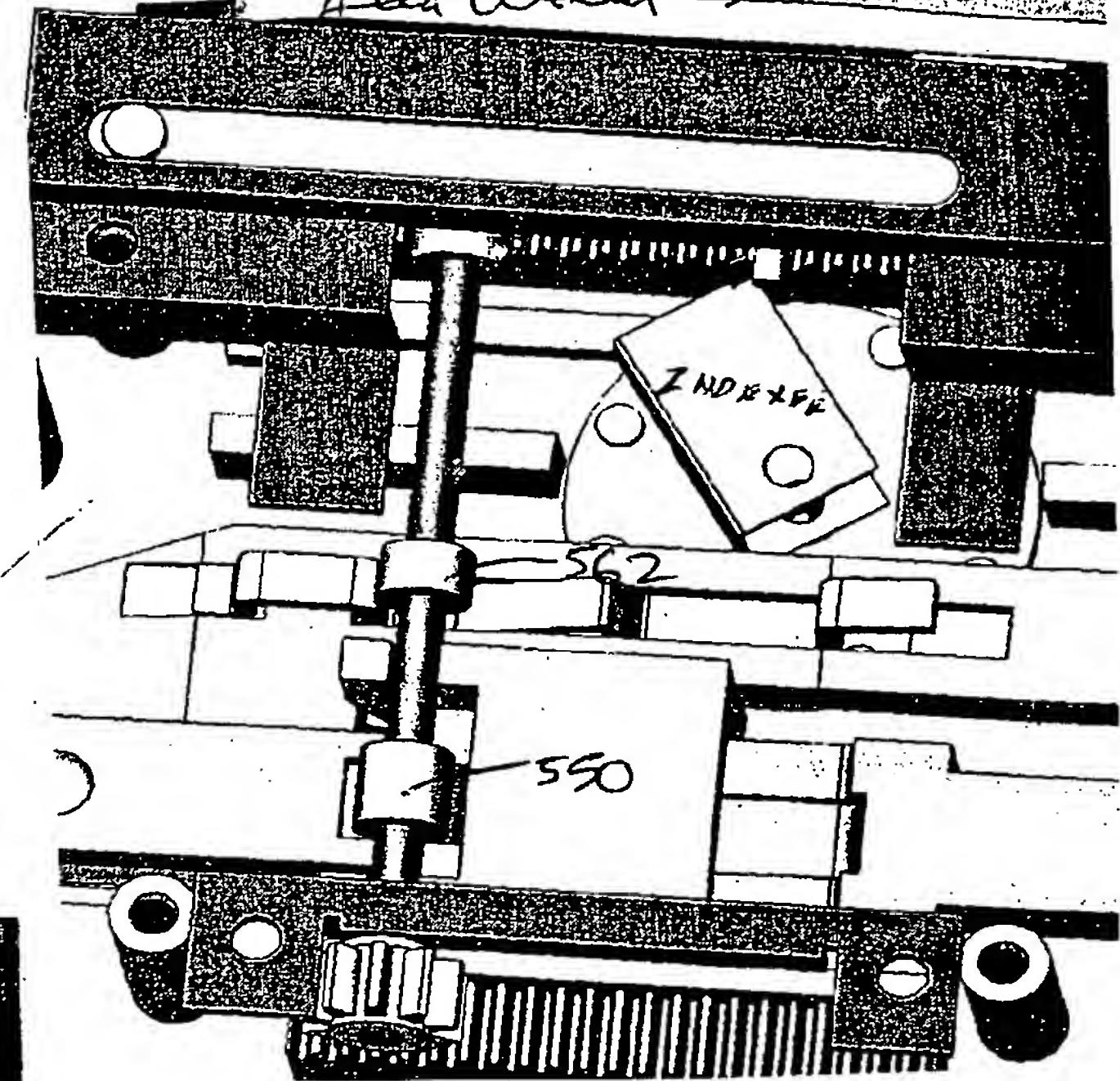


FIG-21

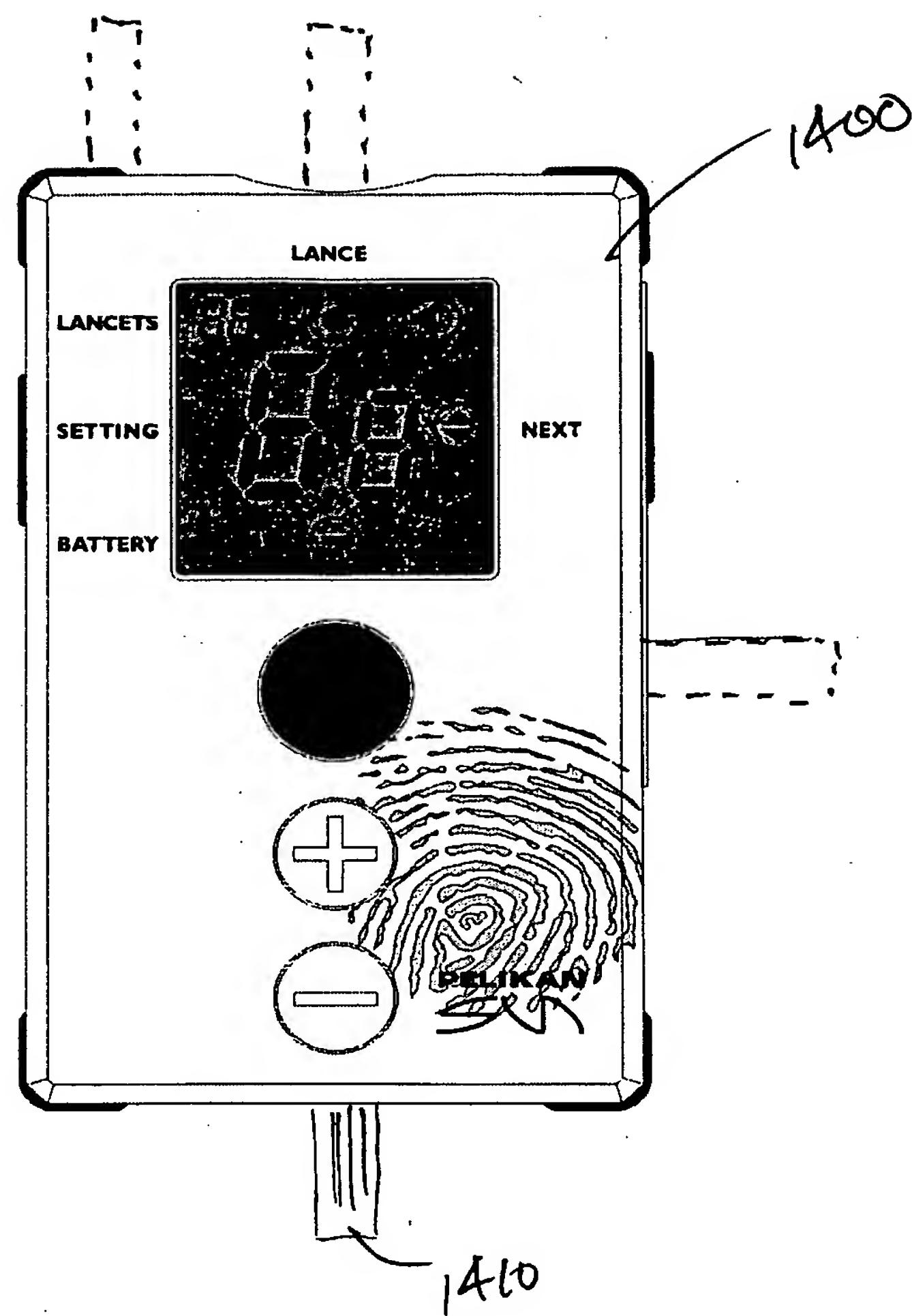


Fig. 22

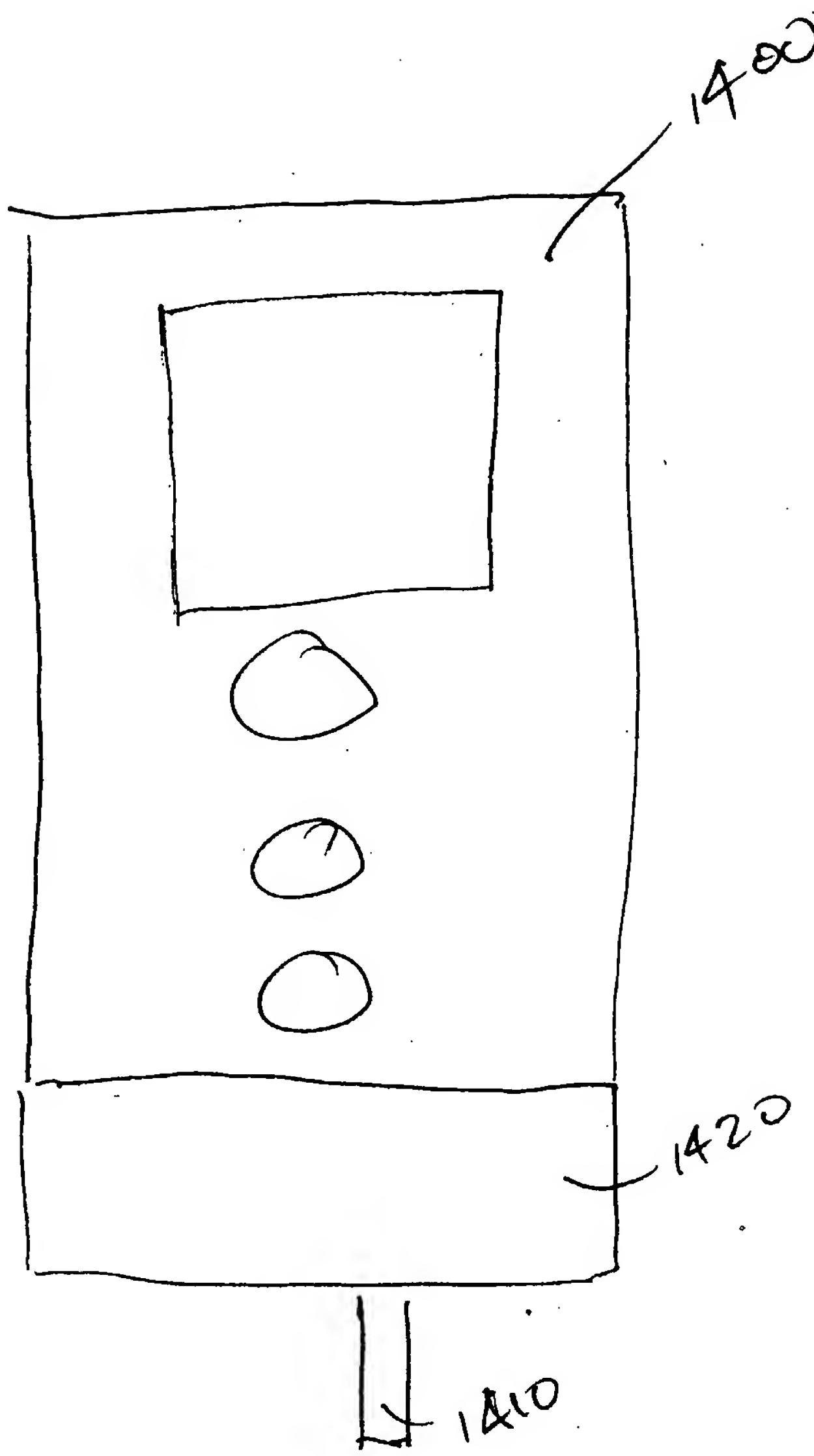
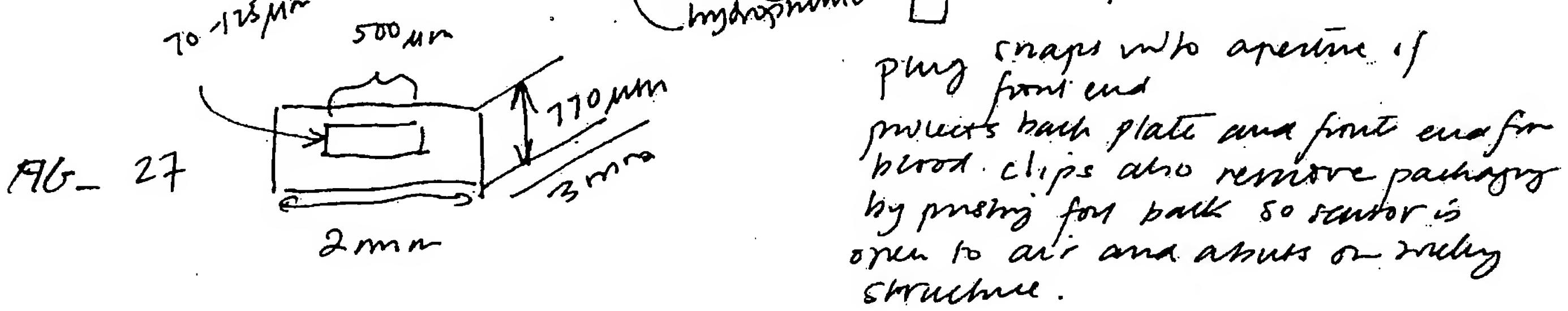
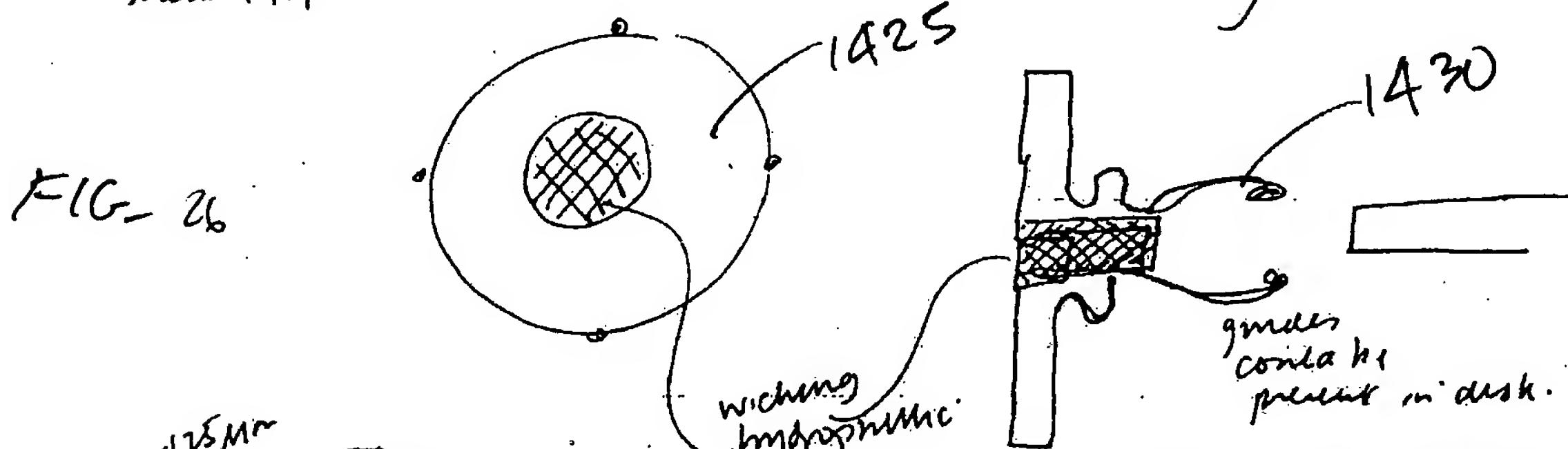
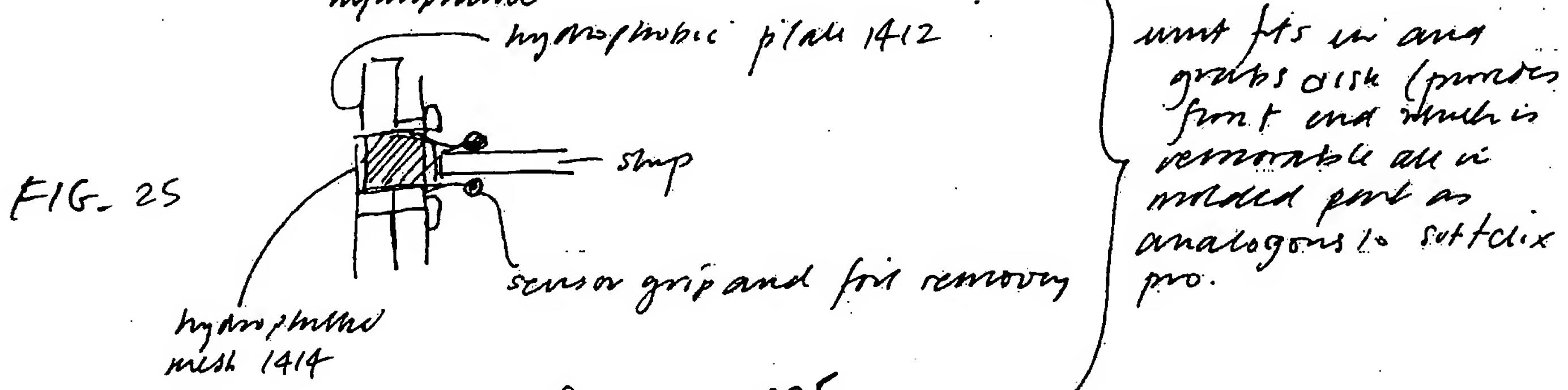
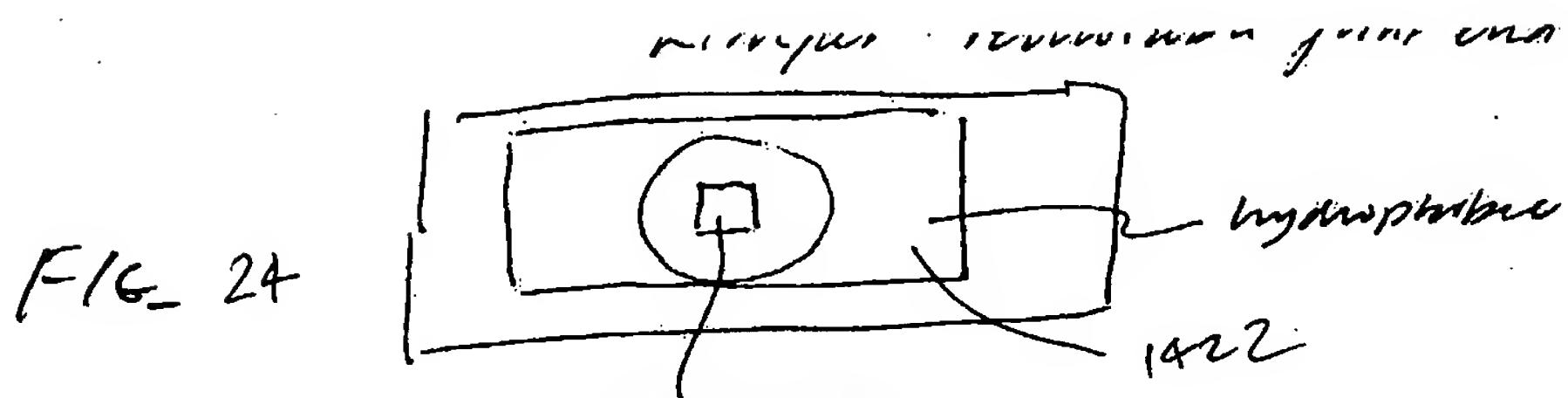
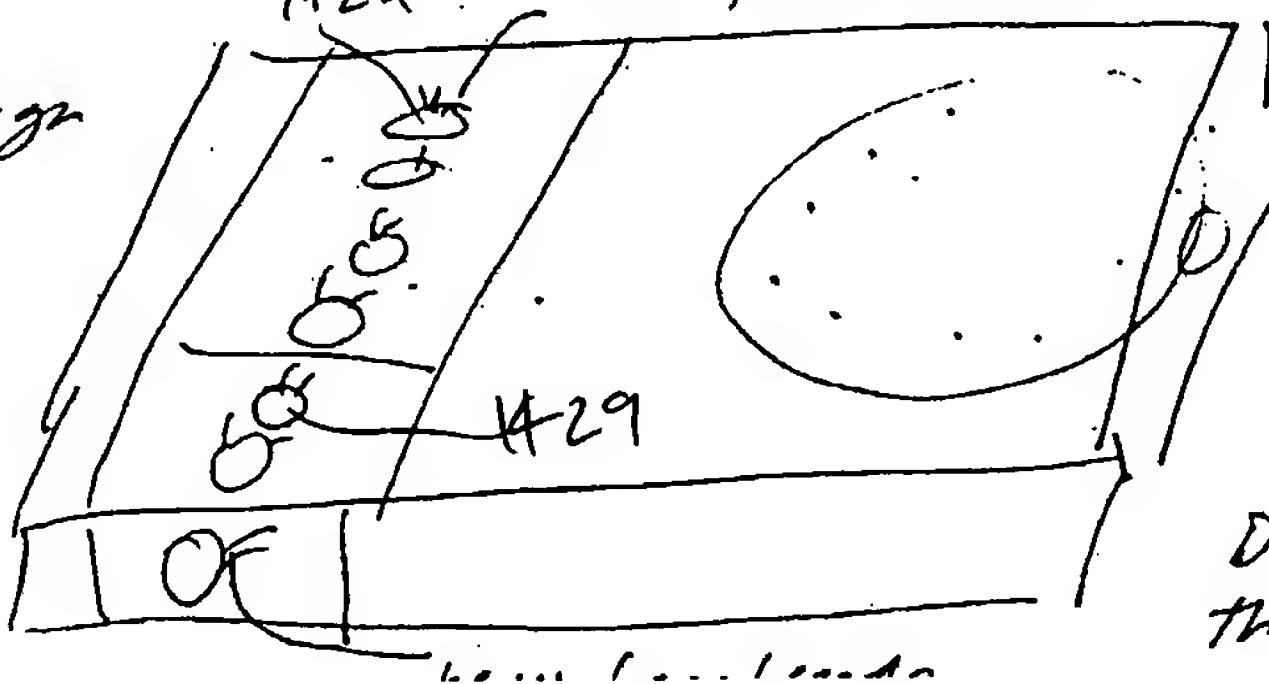


FIG-23



sensor disc may be finger shaped.

well known paradigm
in single device
multi user e.g.
Thermometer,
otoscopes etc.



disposable
front end
stored in area
where capture
need to be
- new dispenser
- old collector.
Disk and front end
thrown out together

FIG-28

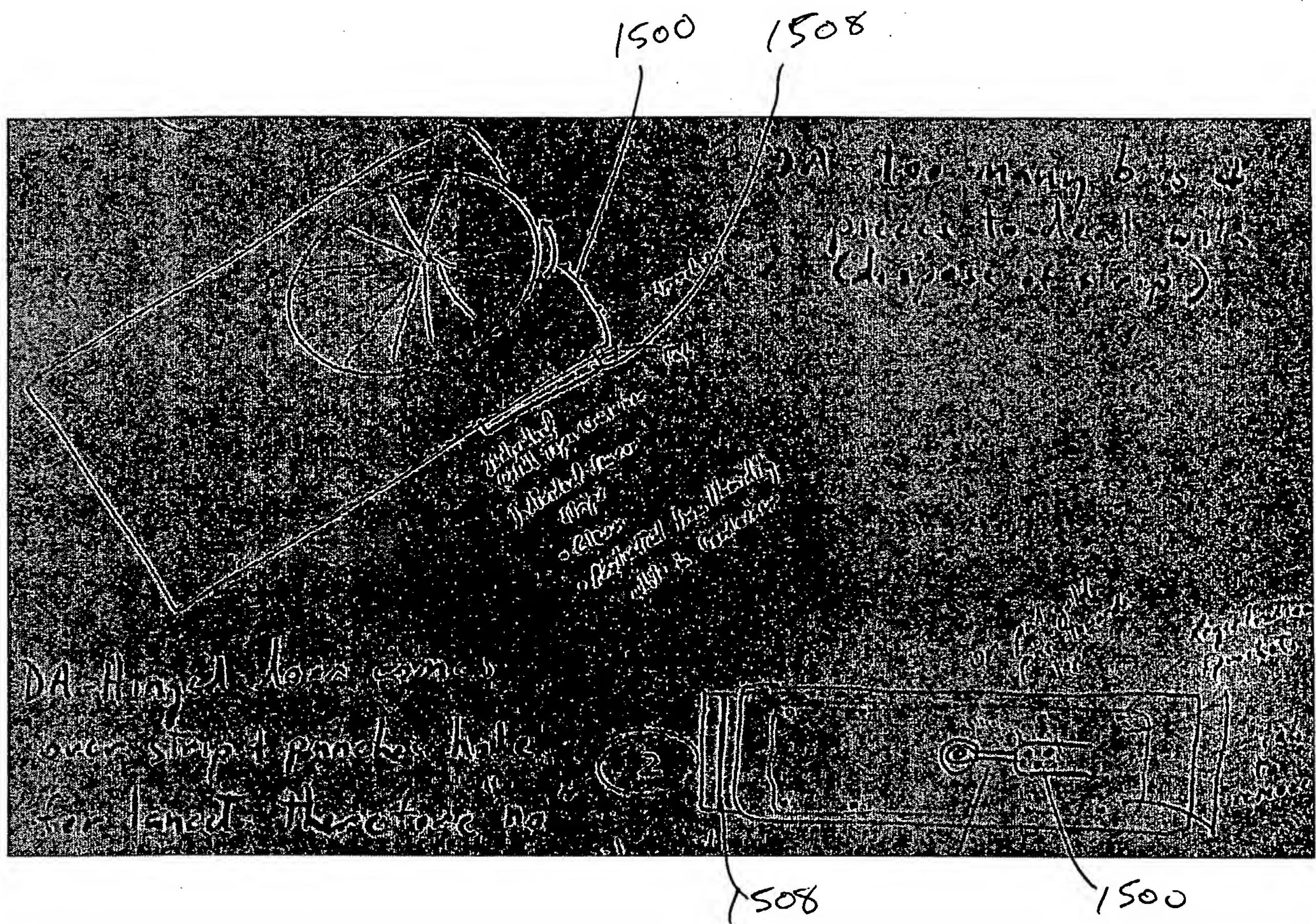


FIG - 29

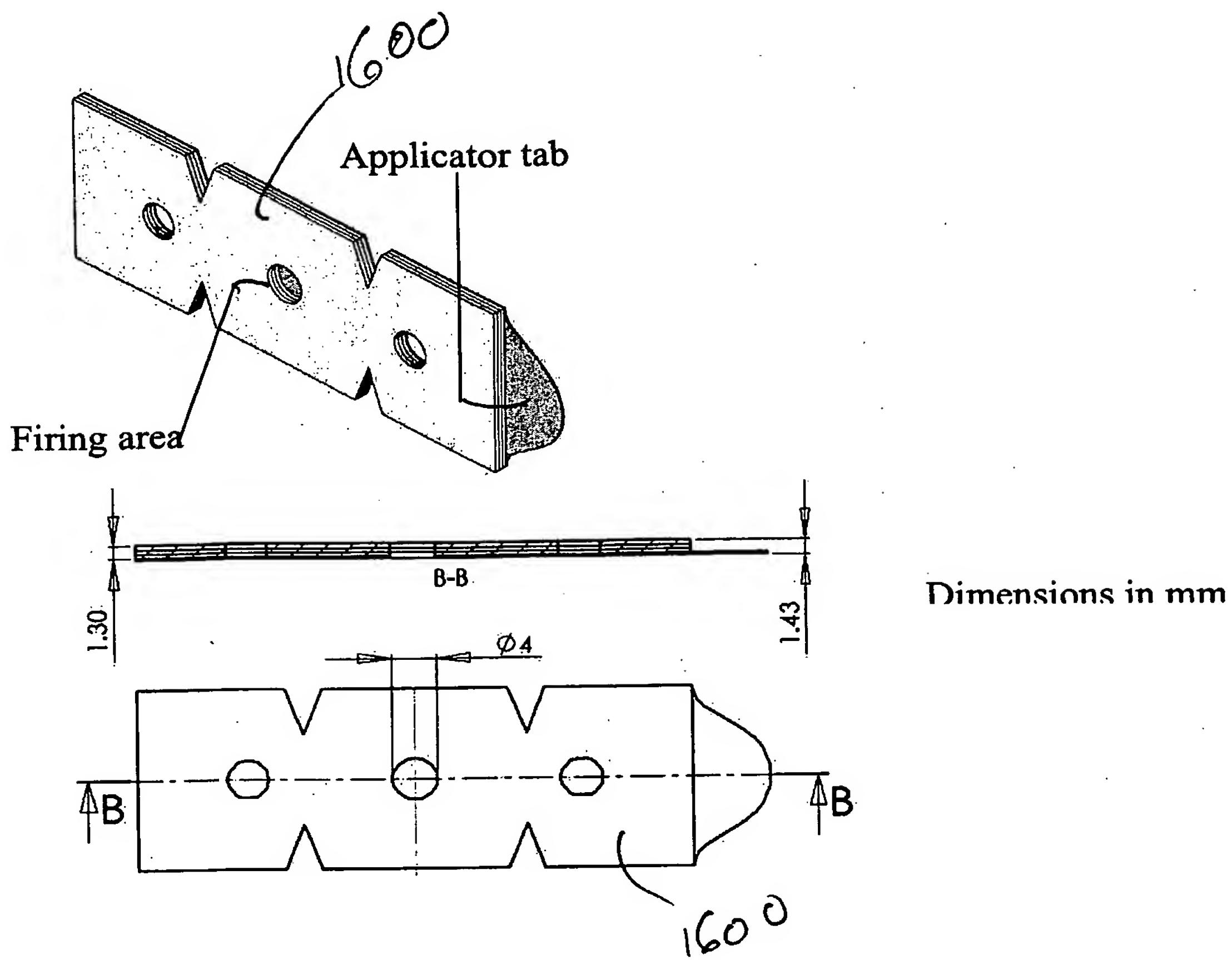


FIG-30

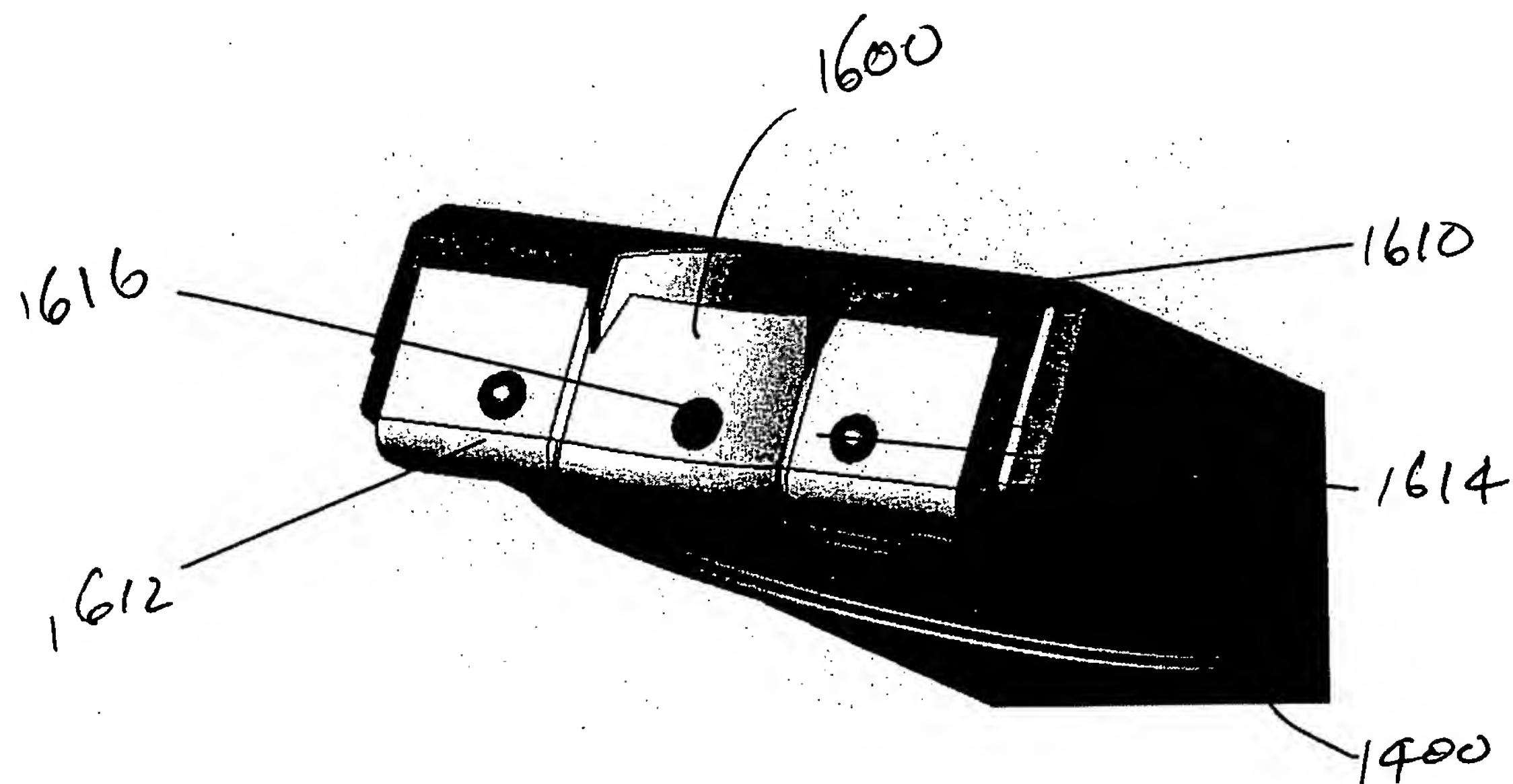
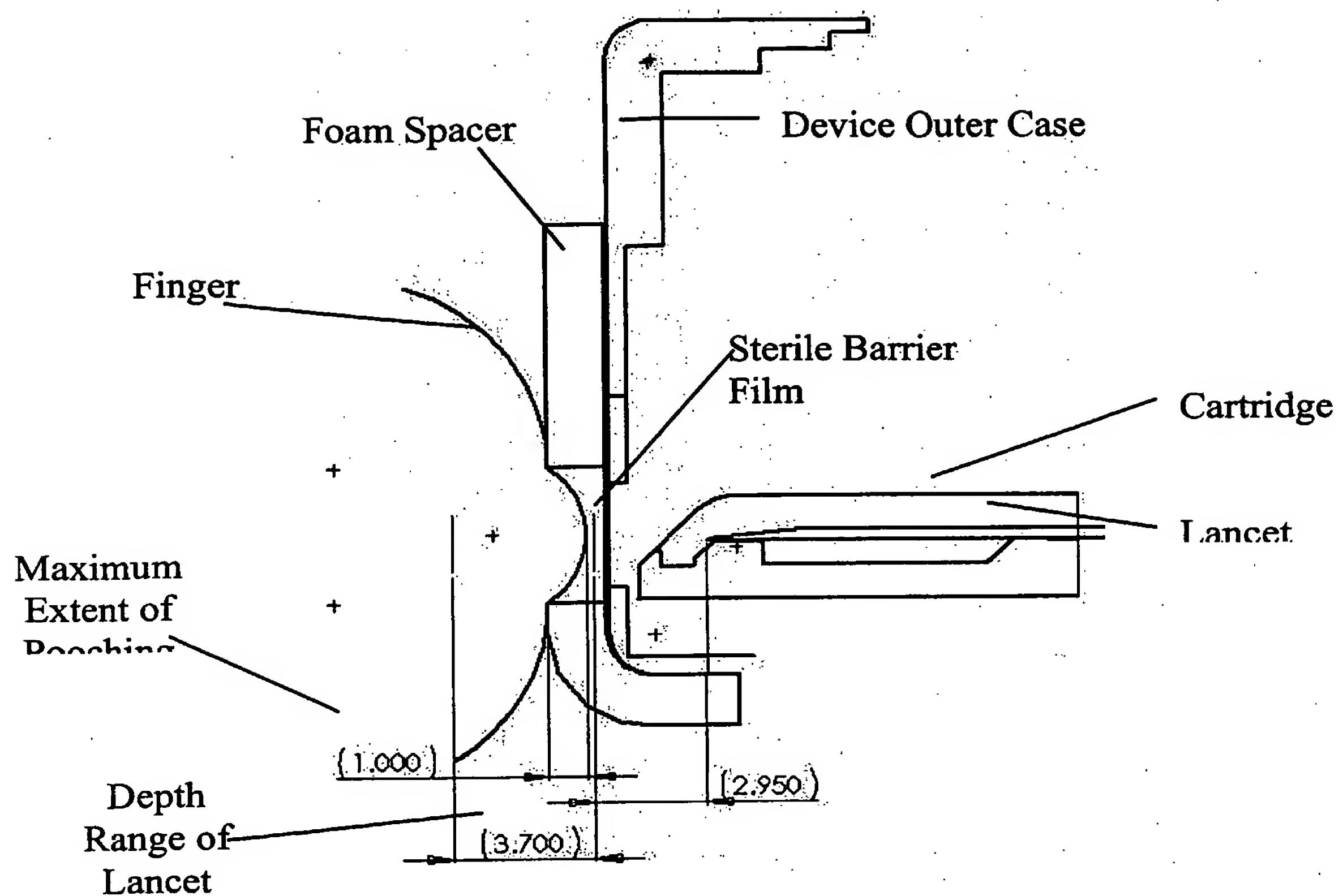
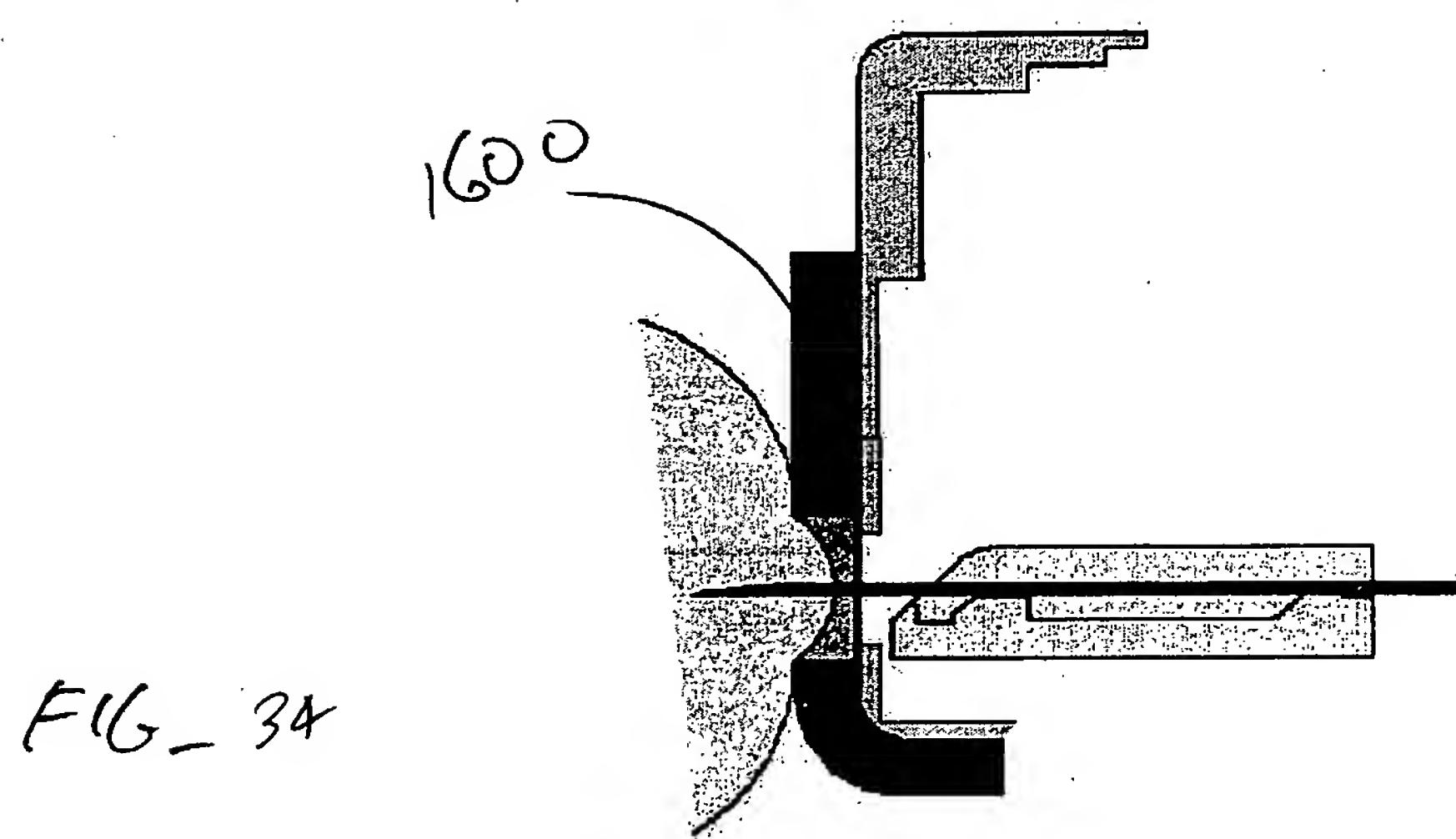
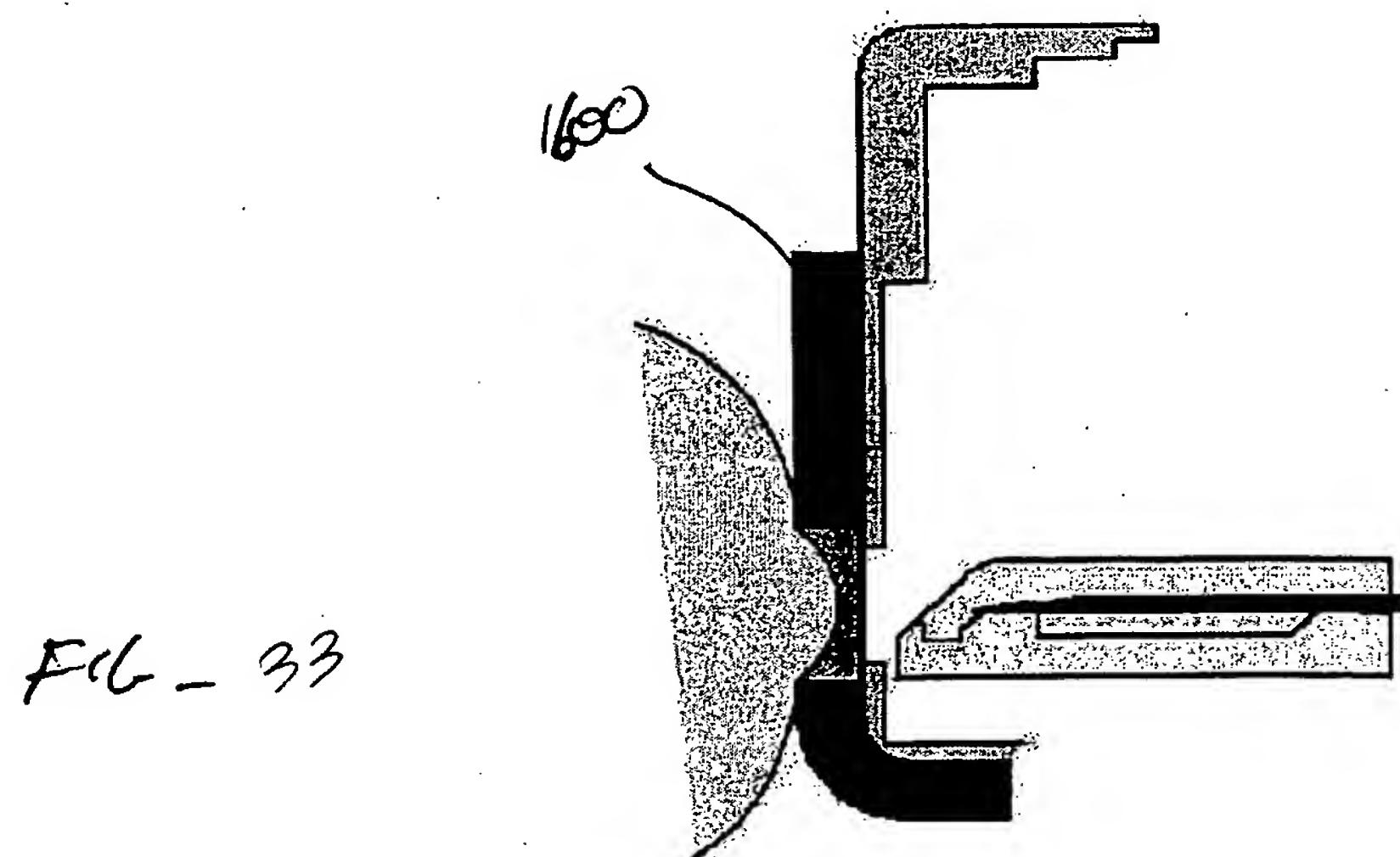


FIG-31





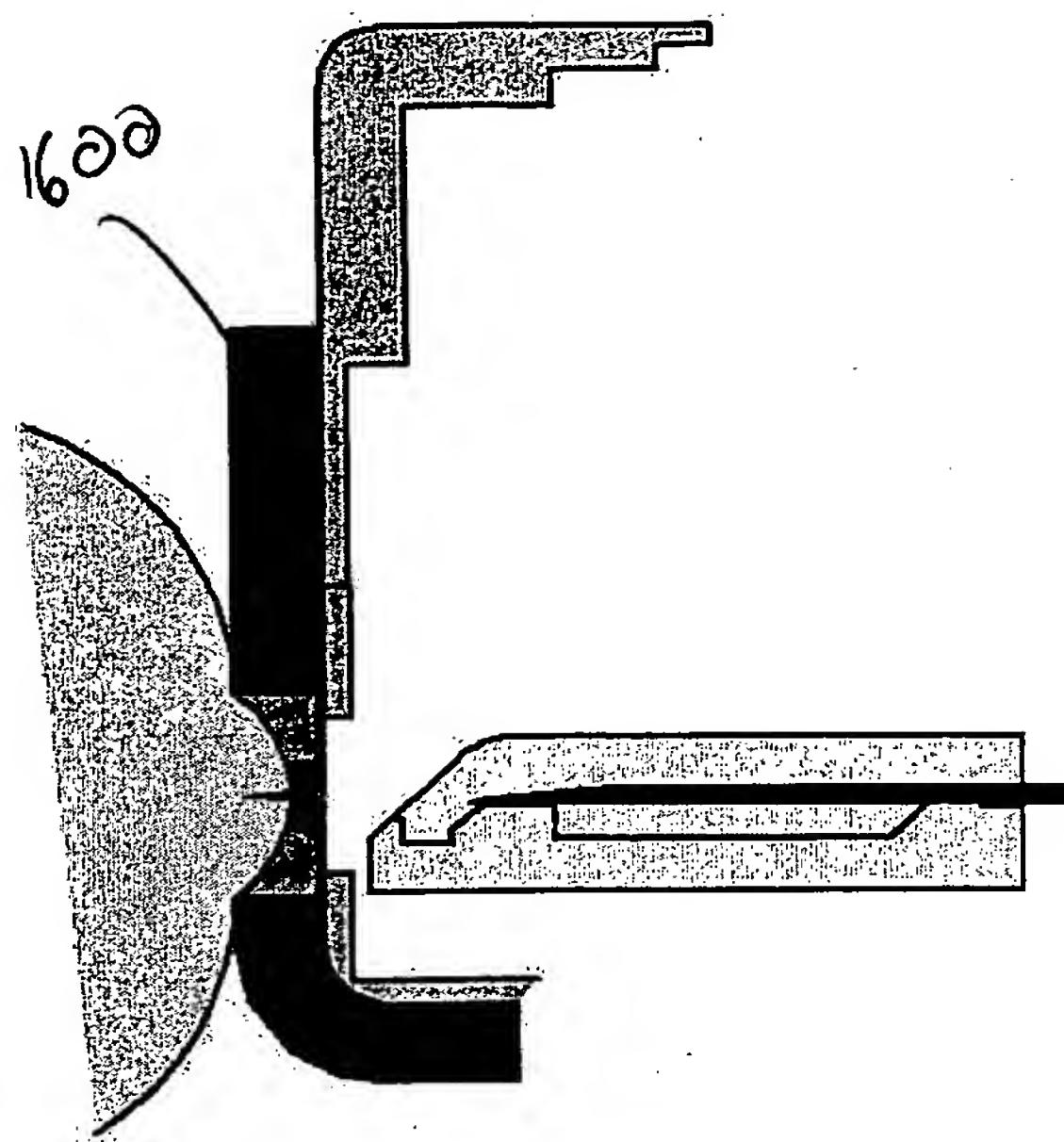


FIG- 35

Puncture
hole

Lancet

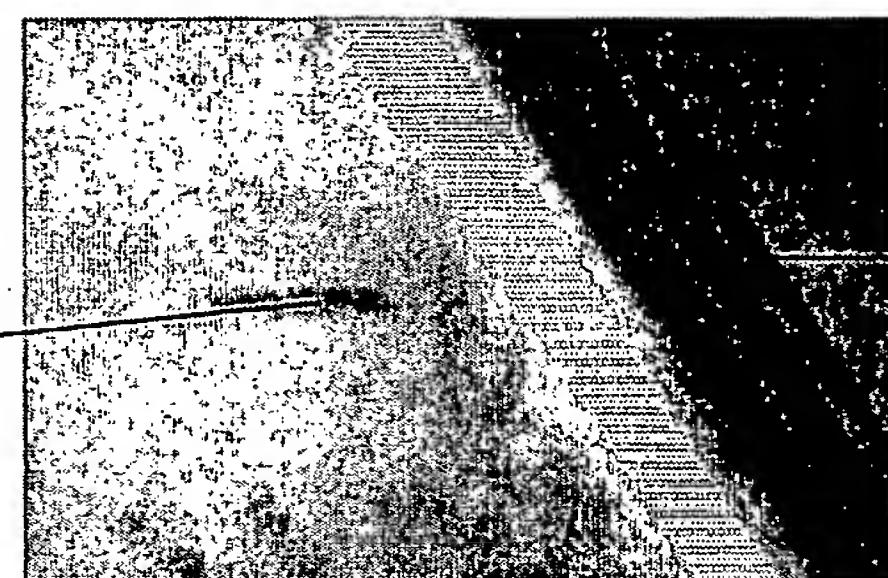
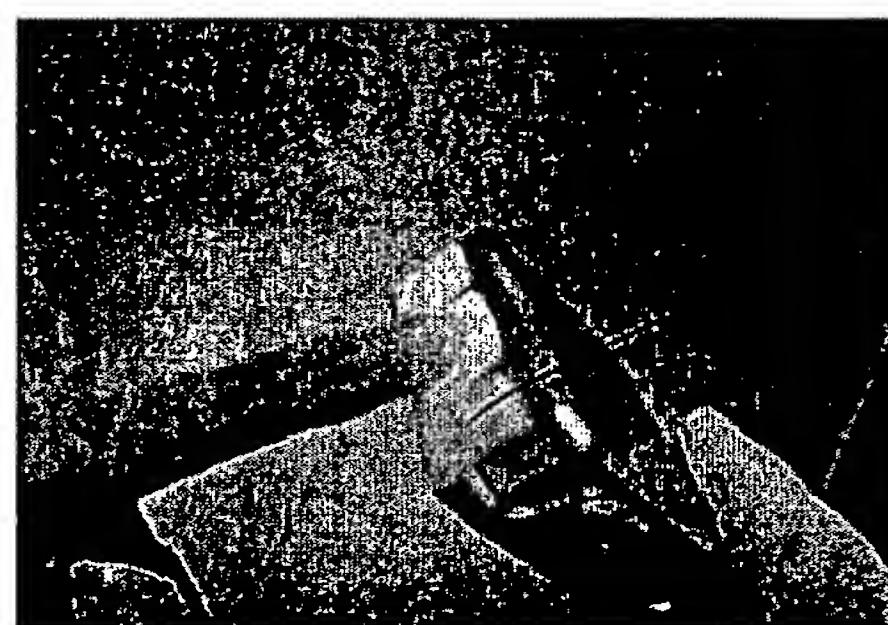


FIG - 36



1600

FIG - 37



FIG - 38



FIG - 39

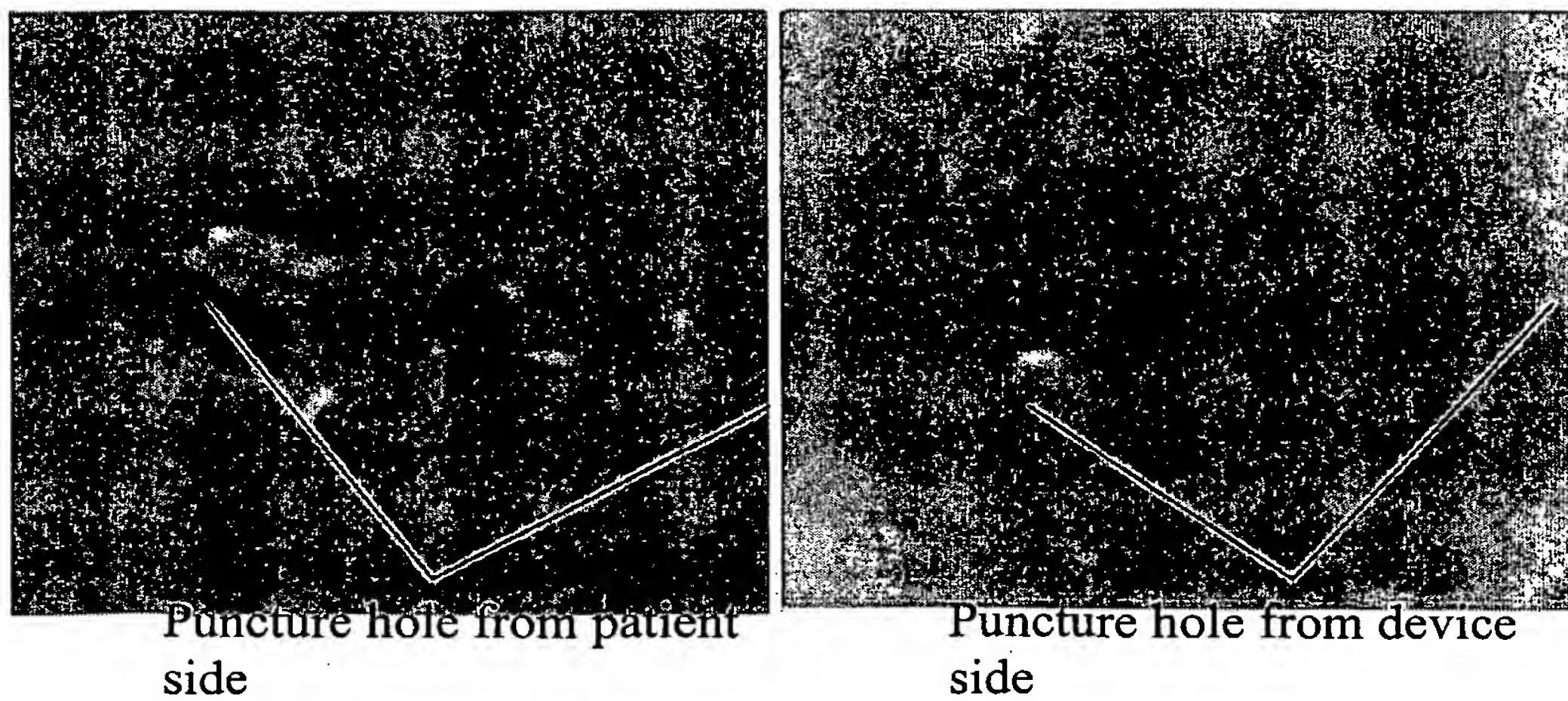


FIG - 40

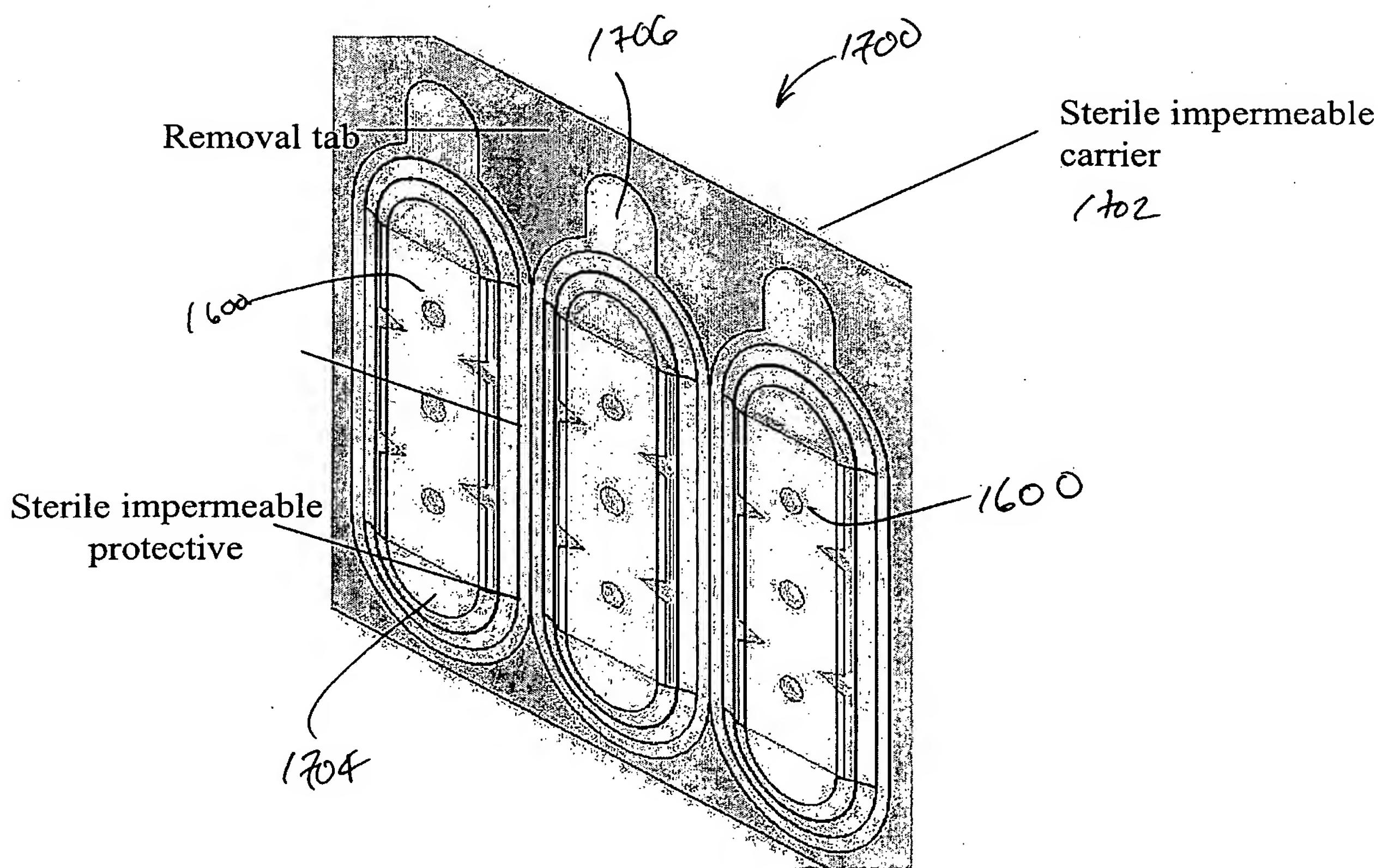


FIG - 41

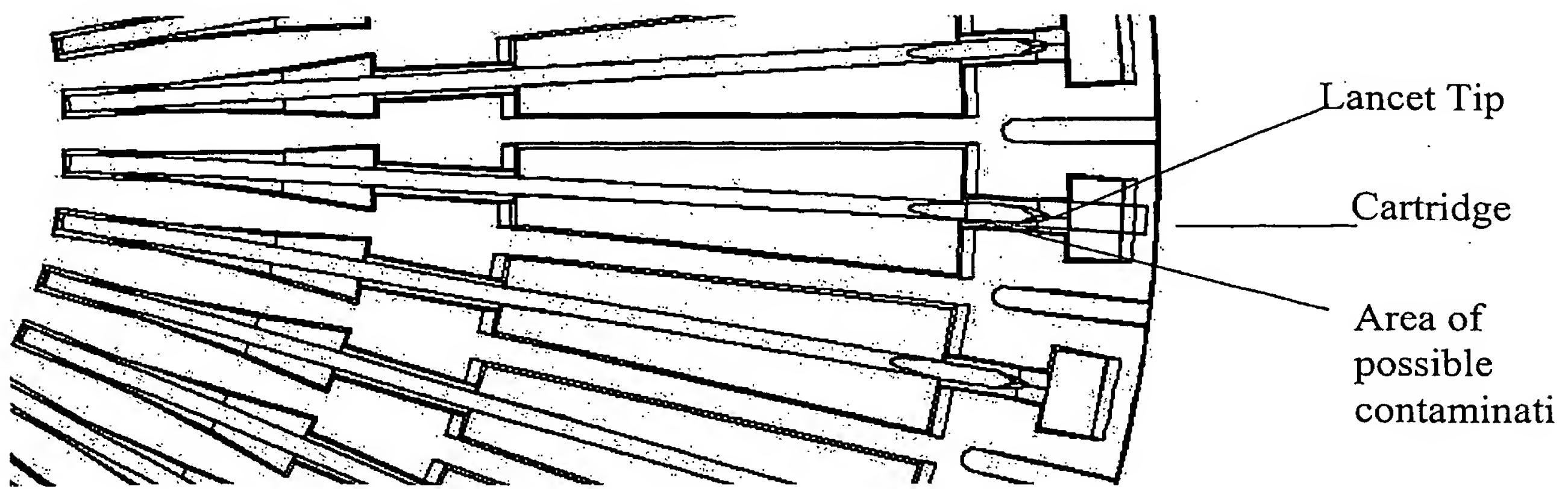


FIG-42

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/19445

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A 61B 17/32
US CL : 606/181; 73/ 863

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/181; 73/ 863

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0098009A1 (BOECKER et al) 20 May 2004, WHole document	1-17
---		-----
Y		18,19

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

06 October 2005 (06.10.2005)

Date of mailing of the international search report

10 NOV 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

Hezron E. Williams

Telephone No. (571) 272-1750